



Almac Simplify™ IRT Training

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Disclosures

- None









Key Objectives

1. Introduction to Almac Services for Protocol CHANGE AFib
2. Accessing Simplify™
 - / Protocol CHANGE AFib Simplify™ Flow
3. Simplify™ User Modules: Subject Transactions
 - / Sample Screenshots
4. Simplify™ User Modules: Subject Transactions
 - / Entering Already-Existing Subjects
5. Simplify™ – Administrative Tasks
 - / My Profile
 - / Analytics
 - / User Accounts
6. Simplify™ User Support

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Overview

-  Introduction to Almac Services for Protocol CHANGE AFib
-  Accessing Simplify™
 - Protocol CHANGE AFib Simplify™ Flow
-  Simplify™ User Modules: Subject Transactions
 - Sample Screenshots
-  Simplify™ User Modules: Subject Transactions – Entering Already-Existing Subjects
-  Simplify™ – Administrative Tasks
 - My Profile
 - Analytics
 - User Accounts
-  Simplify™ User Support

Project Manager

Throughout all project phases

Kathryn Tilley, US/PA

Site Queries

IRTHELP@almacgroup.com

Almac Services

Design

- Study/Site Management
- Subject Management
- Alerts & Views

Support/Maintenance

- User access registration email is automatically generated
- Users are to register as soon as they receive the registration email
- Site and Study Team User Guides to the Simplify™ via Web



Users can contact Almac Technical Support via:

- Phone (local toll-free number)
- Email
- On-line via LiveChat

Being available to you 24/7/365 by various convenient options is important.

Accessing Simplify™


Each User will receive their access information via email

- Access information will contain:
 - 1 x Email to register
 - 1 x Email to access the system after registration



Almac offers an option for clients to allow users to expand single sign-on capabilities to access Simplify™ with their existing Exostar® account.

- Almac Clinical Technologies is currently the only IRT provider in this community.

**IXRS Clinical Trials**
Partnering to advance human health

You have been granted access to:
Client Name - Study Code

If you are already a registered user, simply click below to access your study. If you have not yet completed the user registration process, you will receive another e-mail with a link to direct you. Once your registration is complete, you will be able to access your assigned study.

[Access Study Now](#)

Or copy and paste this link into your browser's address bar:
<https://www.ixrs.com/Global/>

If you have received this email in error, please delete it. No further action is required.

Need Assistance?
Telephone: 1-877-738-8831
Fax: 1-215-660-8620
Email: IVRSSupport@almacgroup.com
<http://www.almacgroup.com>

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Craigavon, BT63 5QD

Login

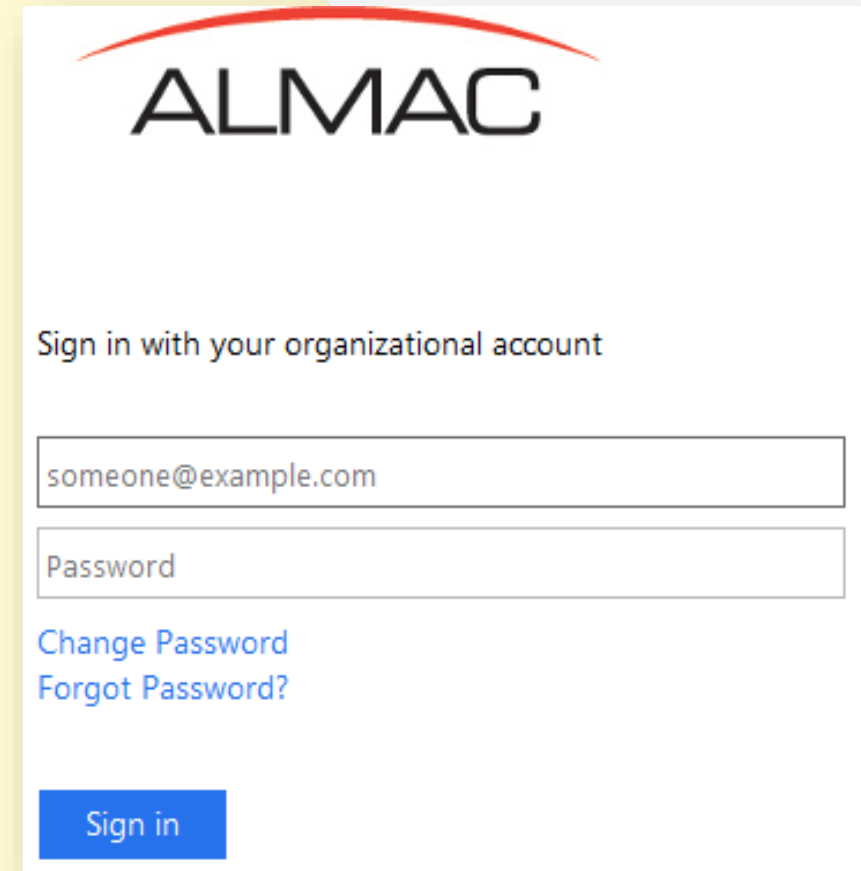


User ID is the user's email address



User sets up password in the UI after using the link in their registration email.

Website: <https://www.ixrs.com>




ALMAC

Sign in with your organizational account

[Change Password](#)
[Forgot Password?](#)

Terms of Use

- User will be required to accept the Terms of Use upon their first entry into Simplify™
- Only need to accept for the first time accessing the system

 IXRS® Clinical Trials
Partnering to advance human health

▼ Natasha.Karkacheva@almacgroup.com

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Please scroll down to review then click 'ACCEPT' to proceed:

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Accessing the Simplify™ Home Page

The Site Dashboard displays subject and supplies related information for your site as well as access to commonly used functions such as Acknowledge Shipment and Subject Screening.

The screenshot displays the Simplify™ Home Page for site 'US 1, USA (4004) [Active]'. The top navigation bar includes links for Home, Study, Subjects, Sites, Supplies, Reports, Analytics, and Users. The main content area is divided into two sections: 'Subjects' and 'Supplies'. The 'Subjects' section shows '8 Total Registered' and includes a search bar with the placeholder 'Enter Subject ID', a 'Find Subject' button, and an 'Enter New Subject' button. The 'Supplies' section shows '0 Available Kits*' and '0 Shipments In Transit', with a red 'NOT APPLICABLE' status. A footnote explains that available kits are those not expired and assignable, excluding quarantined supply or kits on hold. Two purple arrows point from external labels to the 'Enter Subject ID' box and the 'Enter New Subject' button.

Home ▾ Study ▾ Subjects ▾ Sites ▾ Supplies ▾ Reports ▾ Analytics ▾ Users ▾

US 1, USA (4004) [Active] - Change site

Subjects

8
Total Registered

Enter Subject ID

Find Subject

Enter New Subject

Supplies **NOT APPLICABLE**

0
Available Kits*

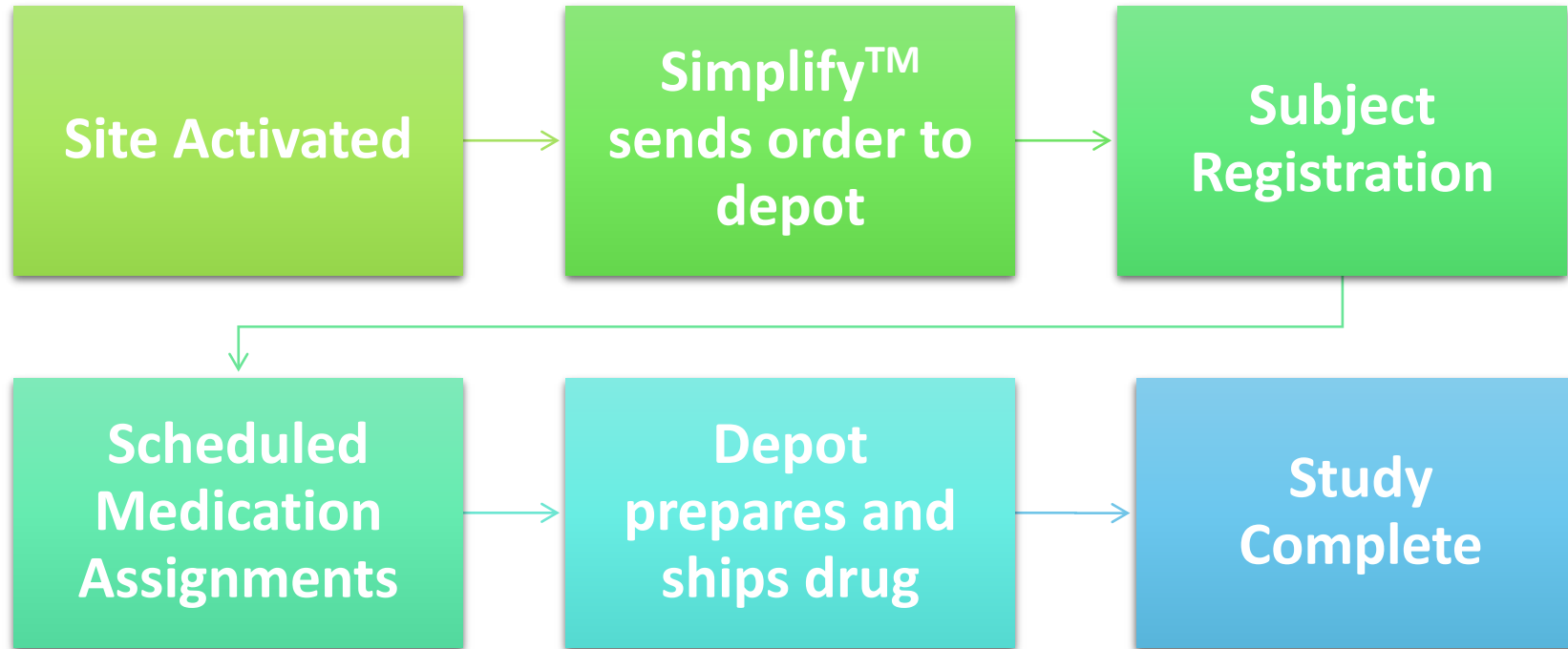
0
Shipments In Transit

*Kits Available at Site that have not expired and are assignable. This count will not include quarantined supply, or kits that are part of lots that are "On Hold for Assignment," or shipments in transit.

Commonly Used Functions

Information Entry Box

CHANGE AFib Simplify™ Flow



Additional Modules:

Skip Visit

Discontinue

Kit
Replacement

CHANGE AFib Simplify™ Visit Schedule

#	Visit Name	Days From Reference Visit	Direct-to-Subject Eligible?	Receive Treatment?	Kit Types	Quantity
1	Registration Assignment Visit			Yes	1 - Multaq (Dronedarone) 400 mg	5
2	Drug Dispensing Event 2	120 days after Registration Assignment Visit	Yes	Yes	1 - Multaq (Dronedarone) 400 mg	5
3	Drug Dispensing Event 3	120 days after Drug Dispensing Event 2	Yes	Yes	1 - Multaq (Dronedarone) 400 mg	5

Roles & Activities / Self Service Functionality

- Roles required for the study and associated activities have been built in to the system.
- This includes a Self Service Functionality.
- The Self Service functionality empowers the study team to be able to control key pieces of IRT functionality like user management, supply release and data correction quickly without having to contact Almac.
- If there are other tasks you require assistance with IRTHelp@almacgroup.com will be happy to assist you.

Simplify™ User Modules: Subject Transactions



Simplify™ Site User Roles



Site Investigator Site Personnel

- All Simplify™ Subject Related Features
- Site Management
- User Accounts – add/modify/ deactivate
- Limited Site Reports

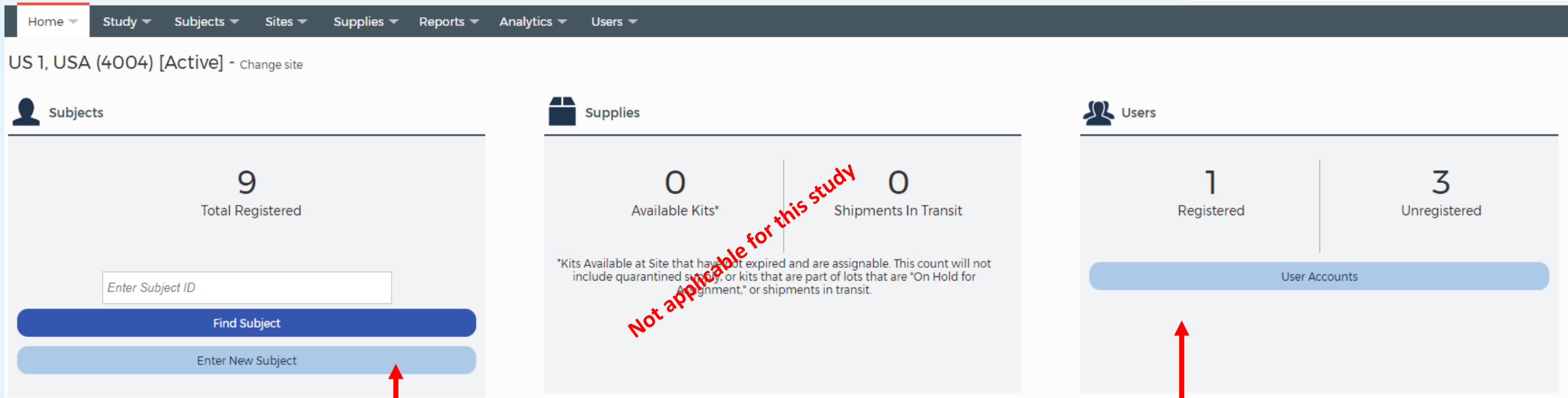


Sponsor/Admin

- Study Management
- Site Management
- Site and Study Reports
- User Accounts – add/modify/ deactivate

Simplify™ Site Dashboard

Menu Bar to select appropriate feature



The dashboard features a dark grey menu bar at the top with the following options: Home, Study, Subjects, Sites, Supplies, Reports, Analytics, and Users. Below the menu bar, the current site is identified as "US 1, USA (4004) [Active] - Change site".

The dashboard is divided into three main sections:

- Subjects:** Displays "9 Total Registered". It includes a search bar labeled "Enter Subject ID", a blue "Find Subject" button, and a light blue "Enter New Subject" button.
- Supplies:** Displays "0 Available Kits*" and "0 Shipments In Transit". A red diagonal watermark reads "Not applicable for this study". A footnote states: "*Kits Available at Site that have not expired and are assignable. This count will not include quarantined supply, or kits that are part of lots that are 'On Hold for Assignment,' or shipments in transit."
- Users:** Displays "1 Registered" and "3 Unregistered". It includes a blue button labeled "User Accounts".

Shortcut options to select existing subject or create new subject

Shortcut option to select User accounts

Site User Simplify™ Transactions Introduction

Register Scheduled Visit for Subject ID CHGAF-4004-1234, US 1, USA (4004)

1. Register Scheduled Visit

2. Review

3. Confirmation

**Confirm correct
Subject is selected**

Visit Information

You have selected to register a scheduled visit.

Subject ID:
CHGAF-4004-1234

Visit Name:
Drug Dispensing Event 2

Target Visit Date:
10-Aug-2023

Is Subject Physically at the Site? *

- ☐ Yes - subject is physically at site for dispensing
- ☐ No - supply will be shipped from depot to subject location

Will supplies be dispensed from site inventory at the next scheduled visit? *

- ☐ Yes - subject will be at site
- ☐ No - supply must be shipped from depot to subject location

Cancel

Next

**Select Cancel or
Next as required**

**All transactions will
have:**

- **Input Screen**
- **Review Screen**
- **Confirmation
Screen**

Site User Simplify™ Transactions Introduction

- The system user will receive an alert email following an IRT transaction.

Examples include:

- Completion of kit assignment
- Correction of Subject's Data
- These Alerts contain the link to the appropriate screens in Web Simplify™ to access pertinent information
- All subject information can be printed or exported from Simplify™, if needed.

Please log in for further details.

Log In

Or copy and paste this link into your browser's address bar:

<https://uat.ixrs.com/Almac111111/Subjects/Edit/17docofb-0aed-4b9f-b79a-a4b2009f9516>

If you have received this email in error, please delete it. No further action is required.

Need Assistance?

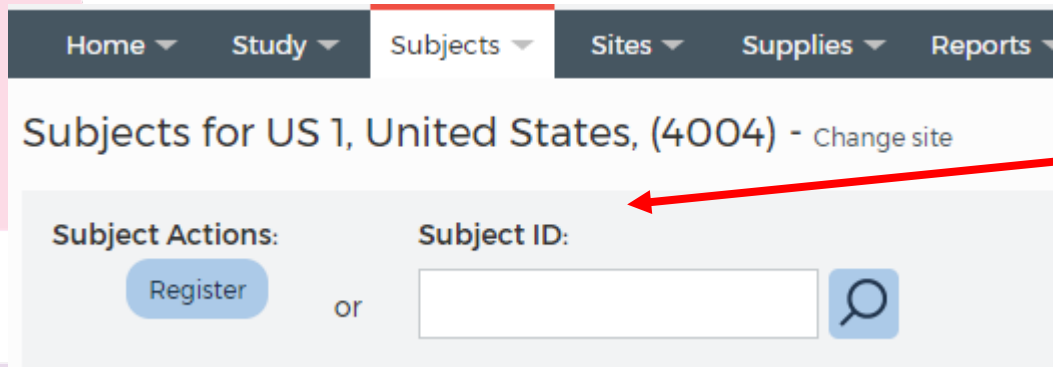
Telephone: 1-877-738-8831

Fax: 1-215-660-8620

Email: IVRSupport@almacgroup.com

<http://www.almacgroup.com>

Site Menu Options in Simplify™



A user can choose to Register a subject or search for a specific Subject ID via the View Subjects screen.

Subjects ▶ Subject CHGAF-4004-0007 (In Treatment)
US 1, USA (4004)

Subject Data

Randomization Date: 4/4/2023

Date of Birth: 01-Jan-1984

Site Code: 4004

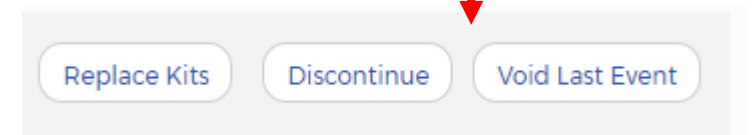
Next Event: Drug Dispensing Event 3

Register Next Visit

Skip

After Registration, Register Next Visit and Skip become available in the Subject Events menu corresponding to a specific Subject ID.

After Registration, additional options are also available – Replace Kits, Discontinue, and Void Last Event.



Site Menu Options in Simplify™

Home
Study
Subjects
Sites
Supplies
Reports
Analytics
Users

Subjects
Subject CHGAF-4004-0007 (In Treatment)
US 1, USA (4004)
Print

Subject Data
Randomization Date: 4/4/2023
Date of Birth: 01-Jan-1984
Site Code: 4004

Next Event: Drug Dispensing Event 3
Register Next Visit
Skip

You can also Edit previous visit data.
Replace Kits
Discontinue
Void Last Event

Subject Events
Kit Assignment History

Click on completed event to view.

Event	Target Date	Event Date	
Registration		12-Apr-2023	Edit
Drug Dispensing Event 2		Skipped	Edit
Drug Dispensing Event 3	08-Dec-2023		

On the Subject Events page, you can view the subject's past and upcoming visits; target dates for the upcoming visit(s) are displayed.

You can also Edit previous visit data.

Site Menu Options in Simplify™

Home
Study
Subjects
Sites
Supplies
Reports
Analytics
Users

Subjects
Subject CHGAF-4004-0007 (In Treatment)
US 1, USA (4004)
Print

Subject Data

Randomization Date: 4/4/2023
Date of Birth: 01-Jan-1984
Site Code: 4004

Next Event: Drug Dispensing Event 3

Register Next Visit
Skip


Subject Events

Replace Kits
Discontinue
Void Last Event

Kit Assignment History

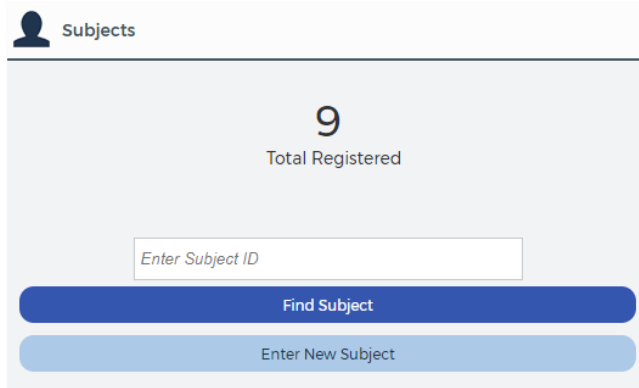
Kit Number	Label Lot Number	Quantity	Visit Assigned	Date Assigned	Date Dispensed	Replaced Kit/Lot Number	Visit Reason	Original Subject Assigned by System
100063	N/A	N/A	Registration Assignment Visit	12-Apr-2023	12-Apr-2023		Scheduled Visit	CHGAF-4004-0007
100064	N/A	N/A	Registration Assignment Visit	12-Apr-2023	12-Apr-2023		Scheduled Visit	CHGAF-4004-0007
100065	N/A	N/A	Registration Assignment Visit	12-Apr-2023	12-Apr-2023		Scheduled Visit	CHGAF-4004-0007
100066	N/A	N/A	Registration Assignment Visit	12-Apr-2023	12-Apr-2023		Scheduled Visit	CHGAF-4004-0007
100067	N/A	N/A	Registration Assignment Visit	12-Apr-2023	12-Apr-2023		Scheduled Visit	CHGAF-4004-0007

On the Kit Assignment History page, you can view the subject's Kit Numbers and when kits were assigned.



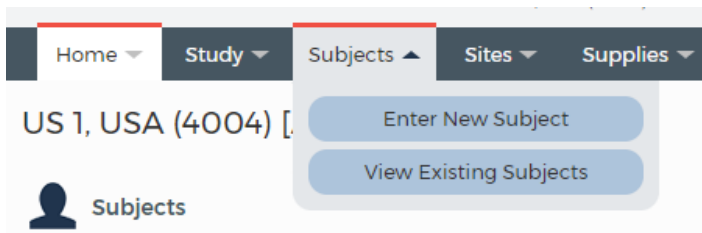
Site User Simplify™ Transactions – Registration

Select Enter New Subject from the Site Dashboard



The screenshot shows the 'Subjects' menu item selected. Below it, a card displays '9 Total Registered'. There is a search bar labeled 'Enter Subject ID' with a 'Find Subject' button. At the bottom of the card is a button labeled 'Enter New Subject'.

or Enter New Subject from the Subjects Menu



The screenshot shows the 'Subjects' menu item selected in a navigation bar. Below the navigation bar, a card displays 'US 1, USA (4004)'. There are two buttons: 'Enter New Subject' and 'View Existing Subjects'.

Register Subject , US 1, USA (4004)

Register Subject

All information is required. *

Registration Details

Subject ID *:

40049997

Date of Birth *:

1982

Randomization Date *:

06 Feb 2023

Is Subject Physically at the Site? *

☐

Yes - subject is physically at site for dispensing

☒

No - supply will be shipped from depot to subject location

Will supplies be dispensed from site inventory at the next scheduled visit? *

☐

Yes - subject will be at site

☒

No - supply must be shipped from depot to subject location

Cancel

Next

Inputs:

- Subject ID – site code + Subject Number
- Date of Birth – Select YEAR of Birth
- Randomization Date – Enter or Select from Calendar
- Is Subject Physically at the Site?
 - NO
- Will supplies be dispensed from the site inventory at the next scheduled visit?
 - NO

Click on Next to continue to the Review page.

Site User Simplify™ Transactions – Registration (continued)

The *Review* page displays.

- **Cancel** – when selected, the current action will be disregarded/canceled
- **Previous** – when selected, you will be brought back to the previous screen where you can make any updates to the data entered
- **Register Subject** – when selected you will move forward to the Confirmation page.

Register Subject , US 1, USA (4004)

Register Subject

Review

Please verify the information below before continuing.

Registration Details

Subject ID:
40049997

Date of Birth:
1982

RandomizationDate:
06-Feb-2023

Is Subject Physically at the Site?

No - supply will be shipped from depot to subject location

Will supplies be dispensed from site inventory at the next scheduled visit?

No - supply must be shipped from depot to subject location

Cancel

Previous

Register Subject

Select Register Subject to move forward with Registration


Site User Simplify™ Transactions – Registration (continued)

The *Confirmation* page displays.

Register Subject

Review

Confirmation

 Subject has been successfully registered.

To generate the shipment to the subject, the site must provide the subject's shipping information to the depot. Please select "Complete Shipment Communication" for each shipment and enter the destination information. Then send the shipment communication to the designated email recipient(s) at the depot. This can also be done from the shipment details at any time.

Shipment 30 - Complete Shipment Communication

Study Information

Study (Protocol):	CHANGE AFib
Client:	American Heart Association Inc
Sponsor:	American Heart Association Inc
Country:	United States
Site Code:	4004
Site Name:	US 1
Investigator:	Title First name Last name

Subject Information

Subject ID:	CHGAF-4004-9997
Date of Birth:	01-Jan-1982
Is Subject Physically at the Site?	No - supply will be shipped from depot to subject location
Will supplies be dispensed from site inventory at the next scheduled visit?	No - supply must be shipped from depot to subject location
Randomization Date:	06-Feb-2023
IRT Registration Date:	14-Apr-2023
Product Assigned:	Multaq (Dronedarone) 400 mg - 100129, 100130, 100131, 100132, 100133

Transaction Details

Transaction Type:	Registration
Local Date and Time:	14-Apr-2023 2:00:18 PM
UTC Date and Time:	14-Apr-2023 18:00:18
Username:	Kathryn Tilley kathryn.tilley@almacgroup.com

View Subject CHGAF-4004-9997

Click on the Shipment [X] – Complete Shipment Communication button to print off drug shipment form.
(The form will display/download as a separate document/window.)

By selecting View Subject [subject ID] button, you will be brought to the Subject Events page for that subject.
**** NOTE – if you did NOT open the Shipment Communication Form, you can still access it via the Supplies menu / Supply Ordering / View Subject Shipments)**

Site User Simplify™ Transactions – Registration (continued)

Shipment Communication Form

AMERICAN HEART ASSOCIATION INC
CHANGE AFib
Blinded Depot-to-Subject Shipment Request Communication

IXRS Shipment Number: 30
Direct-to-Subject: CHGAF-4004-9997
Site: 4004
Site Name: US 1
Investigator Name: First name Last name
Investigator Phone Number: 0123456
Investigator Email: almac@gmail.com

Date Submitted: 14-Apr-2023
Date Expected: 17-Apr-2023

Ship To:

Site to supply subject shipping information.

Please complete and email to:

directtopatient@almacgroup.com

First Name:
Last Name:
Address Line 1:
Address Line 2:
City:
State / Province / Region:
Zip / Postal Code:
Subject Phone #:
Subject Email:
Requested Delivery (AM or PM):

Number Of Kits: 5

Numbered Supply:

100129 100130 100131 100132 100133

Non-Numbered Supply:

Label Lot Number: _____ Quantity: _____

Prescriber Sign-off:

Signature	Print Name	Company and Position	Date

Steps to Take:

1. Print the Form
2. **IN ALL CAPS!** Complete the Subject Demographic Fields (name, address, phone, email)
3. Sign and Date the Form
4. Email the completed form to:
directtopatient@almacgroup.com

Site User Simplify™ Transactions – View/Search Subjects

Select Subjects >> View Existing Subjects. This displays all subjects at the site. Initiate actions for any subject via View Subjects screen

[Home](#) [Study](#) [Subjects](#) [Sites](#) [Supplies](#) [Reports](#) [Analytics](#) [Users](#)

Subjects for US 1, United States, (4004) - [Change site](#)

Subject Actions:

[Register](#) or

[View Analytics](#)

1 - 10 of 10 Results Results Per Page 25 ▼

Subject ID	Date of Birth	Subject Status	Site Code
CHGAF-4004-9999	1980	In Treatment	4004
CHGAF-4004-9998	1981	Study Discontinued	4004
CHGAF-4004-9997	1982	In Treatment	4004
CHGAF-4004-1234	1996	In Treatment	4004

Shortcut to
Existing
Subjects

Site User Simplify™ Transactions – Register Next Visit

Select Subject >> View Subject. Select the required **Subject ID** for activity and select **Register Next Visit**. Enter Visit Information and click on **Next** to proceed with registering the visit.

Home ▾ Study ▾ Subjects ▾ Sites ▾ Supplies ▾ Reports ▾ Analytics ▾ Users ▾

Subjects ▸ Subject CHGAF-4004-9997 (In Treatment)
US 1, USA (4004)

Subject Data

Randomization Date: 2/6/2023
Date of Birth: 01-Jan-1982
Site Code: 4004

Next Event: Drug Dispensing Event 2

Register Next Visit

Skip

Visit Information

You have selected to register a scheduled visit.

Subject ID:
CHGAF-4004-9997

Visit Name:
Drug Dispensing Event 2

Target Visit Date:
12-Aug-2023

Is Subject Physically at the Site? *

☐ Yes - subject is physically at site for dispensing
☐ No - supply will be shipped from depot to subject location

Will supplies be dispensed from site inventory at the next scheduled visit? *

☐ Yes - subject will be at site
☐ No - supply must be shipped from depot to subject location

Cancel

Next

Inputs:

- Is Subject Physically at the Site?
 - NO
- Will supplies be dispensed from the site inventory at the next scheduled visit?
 - NO

Site User Simplify™ Transactions – Register Next Visit (continued)

From the **Review** page, select **Register Scheduled Visit** to proceed.

On the **Confirmation** page, select the Shipment [X] – Complete Shipment Communication button to print, complete, and email the form.

Register Scheduled Visit for Subject ID CHGAF-4004-9997, US 1, USA (4004)

1. Register Scheduled Visit

2. Review

Please verify the information below before continuing.

Visit Information

You have selected to register a scheduled visit.

Subject ID:
CHGAF-4004-9997

Date of Birth:
01-Jan-1982

Visit Name:
Drug Dispensing Event 2

Target Visit Date:
12-Aug-2023

Is Subject Physically at the Site?
No - supply will be shipped from depot to subject location

Will supplies be dispensed from site inventory at the next scheduled visit?
No - supply must be shipped from depot to subject location

Cancel

Previous

Register Scheduled Visit

1. Register Scheduled Visit


✓

Visit has been successfully registered. Drug I

To generate the shipment to the subject, the site r
recipient(s) at the depot. This can also be done fro

Shipment 31 - Complete Shipment Communication

Study Information



Simplify™

Site User Simplify™ Transactions – Skip Visit

Select Subject >> View Subject. Select the required **Subject ID** for activity and select **Skip**.
Click on **Skip Visit** to confirm the action.
You will see the **Skipped** visit in the subject's Events.

1 Subjects ▶ Subject CHGAF-4004-9997 (In Treatment)
US 1, USA (4004)

Subject Data

Randomization Date: 2/6/2023
Date of Birth: 01-Jan-1982
Site Code: 4004

Next Event: Drug Dispensing Event 3

Register Next Visit **Skip**

2

Skip Visit: Drug Dispensing Event 3

You are about to skip a scheduled visit. Do you wish to skip this visit and register the next visit?

Cancel **Skip Visit**

3

Event	Target Date	Event Date	
Registration		14-Apr-2023	Edit
Drug Dispensing Event 2		14-Apr-2023	Edit
Drug Dispensing Event 3		Skipped	Edit

Site User Simplify™ Transactions – Replace Kits

Select Subject >> View Subject. Select the required **Subject ID** for activity and select **Replace Kits**. Click on the box(es) for the kits to replace; select “No” to ***Is Subject Physically at Site***; and click on **Select**.

Subjects ▶ Subject CHGAF-4004-9997 (In Treatment)
US 1, USA (4004)



Visit has been registered as SKIPPED: Drug Dispensing Event 3

Subject Data

Randomization Date: 2/6/2023

Date of Birth: 01-Jan-1982

Site Code: 4004

Replace Kits

Discontinue

Complete Study

Void Last Event

Kit Replacement for Subject ID CHGAF-4004-9997, US 1, USA (4004)



1. Select Kits

2. Review

3. Confirmation

Please select the kit(s) you would like to replace.

Kit Number	Visit Assigned	Date Assigned	Replaced Kit #	Visit Reason
<input checked="" type="checkbox"/> 100134	Drug Dispensing Event 2	14-Apr-2023		Scheduled Visit
<input type="checkbox"/> 100135	Drug Dispensing Event 2	14-Apr-2023		Scheduled Visit
<input checked="" type="checkbox"/> 100136	Drug Dispensing Event 2	14-Apr-2023		Scheduled Visit
<input type="checkbox"/> 100137	Drug Dispensing Event 2	14-Apr-2023		Scheduled Visit
<input type="checkbox"/> 100138	Drug Dispensing Event 2	14-Apr-2023		Scheduled Visit

Is Subject Physically at the Site? *

☐ Yes - subject is physically at site for dispensing

☒ No - supply will be shipped from depot to subject location

Cancel

Select

Site User Simplify™ Transactions – Replace Kits (continued)

Confirm the kits to be replaced; click on **Replace**.

From the **Audit Trail** window, select the ***Reason for Change***; click on **Continue**.

Kit Replacement for Subject ID CHGAF-4004-9997, US 1, USA (4004)

1. Select Kits

2. Review

3. Confirmation



You are about to replace the following for Subject CHGAF-4004-9997. This will assign new kit(s) to this subject. Do you wish to proceed?

Kit Number	Visit Assigned	Date Assigned	Replaced Kit #	Visit Reason
100134	Drug Dispensing Event 2	14-Apr-2023		Scheduled Visit
100136	Drug Dispensing Event 2	14-Apr-2023		Scheduled Visit

Is Subject Physically at the Site?

No - supply will be shipped from depot to subject location

Cancel

Replace

Audit Trail

Reason for Change *

Damaged by Subject

Reference Number

For internal use only

Cancel

Continue

Reasons for Change:

- Damaged by Subject
- Damaged in Transit
- Lost in Transit
- Not Available at Depot

Site User Simplify™ Transactions – Discontinue

Select Subject >> View Subject. Select the required **Subject ID** for activity and select **Discontinue**. Enter the Discontinuation Date and select Reason from the drop-down; click on Continue. Review the Discontinuation details; click on Discontinue Subject.

1

Subjects ▶ Subject CHGAF-4004-9997 (In Treatment)
US 1, USA (4004) Print

✓ Visit has been registered as SKIPPED: Drug Dispensing Event 3

Subject Data

Randomization Date: 2/6/2023
Date of Birth: 01-Jan-1982
Site Code: 4004

Replace Kits **Discontinue** Complete Study Void Last Event


2

Discontinue Subject
Subject ID CHGAF-4004-9998, US 1, USA (4004)

1. Discontinue Subject 2. Review

All information is required. *

Subject Status

Discontinuation Date * DD MMM YYYY 

Reason * --Select--

Cancel **Continue**

3

Discontinue Subject
Subject ID CHGAF-4004-9998, US 1, USA (4004)

1. Discontinue Subject 2. Review

Please verify the information below before continuing.

Subject Status


Discontinuation Date:
14-Apr-2023
Reason:
Withdrew consent


Cancel Edit **Discontinue Subject**

Site User Simplify™ Transactions – Complete Study

Select Subject >> View Subject. Select the required **Subject ID** for activity and select **Complete Study**.
Enter **Study Completion Date**; click on **Continue**.
Confirm study completion and click on **Complete Study**.





1

Subjects ▶ Subject CHGAF-4004-9997 (In Treatment)
US 1, USA (4004)  Print

 Visit has been registered as SKIPPED: Drug Dispensing Event 3

Subject Data

Randomization Date: 2/6/2023
Date of Birth: 01-Jan-1982
Site Code: 4004


2

Complete Study
Subject ID CHGAF-4004-9997, US 1, USA (4004)



1. Complete Study 2. Review

All information is required. *

Subject Status

Study Completion Date * 

DD MMM YYYY

3



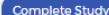
Complete Study
Subject ID CHGAF-4004-9997, US 1, USA (4004)

1. Complete Study

Please verify the information below before continuing.

Subject Status

Study Completion Date *: 14-Apr-2023

Site User Simplify™ Transactions – Void Last Event

Select Subject >> View Subject. Select the required **Subject ID** for activity and select **Void Last Event**. From the **Audit Trail** window, select the ***Reason for Void of Last...Subject Event***; click on **Void**.

Subjects ▶ Subject CHGAF-4004-9997 (In Treatment)
US 1, USA (4004) Print

✓ Visit has been registered as SKIPPED: Drug Dispensing Event 3

Subject Data

Randomization Date: 2/6/2023
Date of Birth: 01-Jan-1982
Site Code: 4004

Replace Kits Discontinue Complete Study **Void Last Event**

Audit Trail

Reason for Void of Last Skipped Visit Subject Event *

Transaction Completed in Error.

Reference Number:

For internal use only

Cancel Void

NOTES:

- There is only one ***Reason for Void***
 - Transaction Completed in Error
- The event that was voided will no longer appear on the ***Subject Events*** page for that subject.

Supplies – Supply Ordering / View Subject Shipments

Select the **Supplies** menu, then select **Supply Ordering / View Subject Shipments**.

Search for the Shipment by entering the **Shipment Number** and/or **Subject ID**; click on the magnifying glass icon.

*** For additional Search options, click on **More Search Options**; click on **Search**.



Home ▾ Study ▾ Subjects ▾ Sites ▾ Supplies ▴ Reports ▾ Analytics ▾

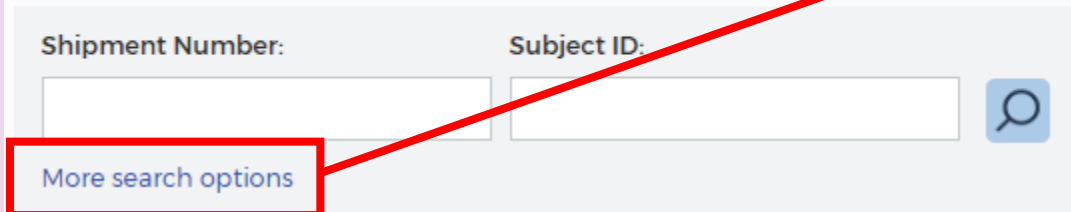
Subjects ▸ Subject CHGAF-4004-99
JS 1, USA (4004)

Subject Data


Randomization Date: 2/6/2023

Supply Ordering ▾
View Site Orders
View Subject Shipments

Shipments ▸ Subject Shipments

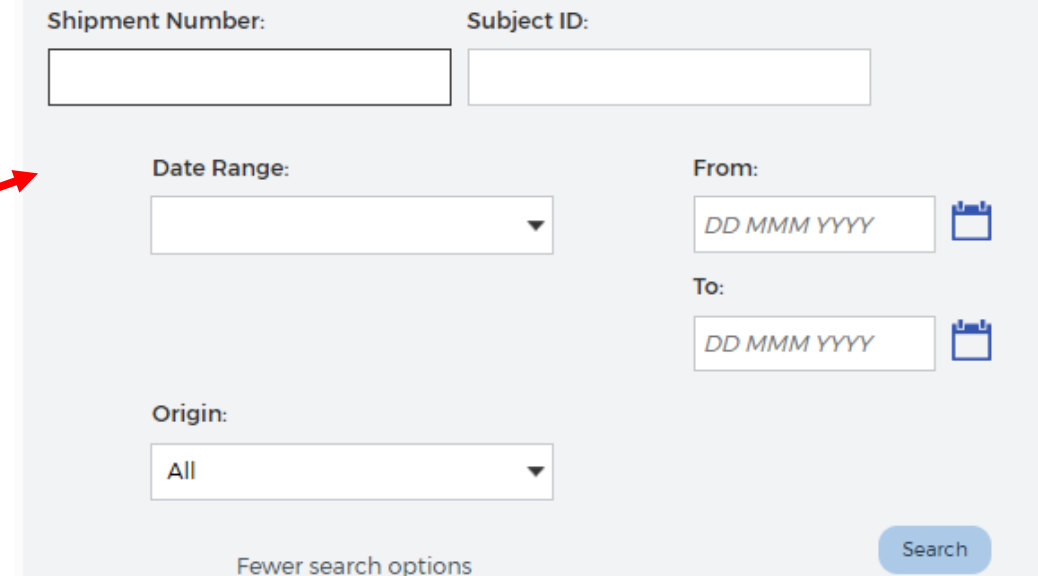


Shipment Number: Subject ID:




More search options


Shipments ▸ Subject Shipments



Shipment Number: Subject ID:

Date Range: ▾

From: 

To: 

Origin: ▾

Fewer search options

Supplies – Supply Ordering / View Subject Shipments (continued)

Based on the Search criteria, a list of shipments will display.

Click on the **Shipment Number** to view the specific details of that shipment.

Shipment Number	Submitted Date	Expected Date	Origin	Subject ID	Event
31	14-Apr-2023	17-Apr-2023	US Depot 1, USA (I)	CHGAF-4004-9997	Drug Dispensing Event 2
30	14-Apr-2023	17-Apr-2023	US Depot 1, USA (I)	CHGAF-4004-9997	Enrollment
29	14-Apr-2023	14-Apr-2023	US Depot 1, USA (I)	CHGAF-4004-9998	Kit Replacement
28	14-Apr-2023	14-Apr-2023	US Depot 1, USA (I)	CHGAF-4004-9998	Enrollment
27	13-Apr-2023	14-Apr-2023	US Depot 1, USA (I)	CHGAF-4004-0004	Kit Replacement
26	13-Apr-2023	14-Apr-2023	US Depot 1, USA (I)		
25	13-Apr-2023	14-Apr-2023	US Depot 1, USA (I)		
24	13-Apr-2023	14-Apr-2023	US Depot 1, USA (I)		
23	13-Apr-2023	14-Apr-2023	US Depot 1, USA (I)		
21	13-Apr-2023	14-Apr-2023	US Depot 1, USA (I)		

123Nex

Shipment

Shipment Number:
31
Vendor Reference Number:
N/A
Shipment Status:
Submitted
Submitted Date (local to Origin):
14-Apr-2023
Shipped Date (local to Origin):
N/A

Origin and Destination

From Depot:
US Depot 1, USA (I)
To Subject:
CHGAF-4004-9997
Subject Site:
US 1, 4004 (USA)

Additional Details

Event:
Drug Dispensing Event 2
Reason:
N/A
Expected Date (local to Destination):
17-Apr-2023

Contents

Numbered Supplies

Kit Quantity (5)

100134	100135	100136	100137
100138			

Shipment Details include:

- Shipment
- Origin and Destination
- Additional Details
- Contents

Supplies – Supply Ordering / View Subject Shipments (continued)

In the upper right-hand corner, click on **Click here to download the latest DOF.**

The DOF will display; follow the directions for completing, signing, and emailing the DOF.

[Click here to download the latest DOF](#)

AMERICAN HEART ASSOCIATION INC
CHANGE AFib
Blinded Depot-to-Subject Shipment Request Communication

IXRS Shipment Number:	31	Date Submitted:	14-Apr-2023
Direct-to-Subject:	CHGAF-4004-9997	Date Expected:	17-Apr-2023
Site:	4004		
Site Name:	US 1		
Investigator Name:	First name Last name		
Investigator Phone Number:	0123456		
Investigator Email:	almac@gmail.com		

Ship To:

Site to supply subject shipping information.
Please complete and email to:

directtopatient@alamacgroup.com

First Name:	<input type="text"/>
Last Name:	<input type="text"/>
Address Line 1:	<input type="text"/>
Address Line 2:	<input type="text"/>
City:	<input type="text"/>
State / Province / Region:	<input type="text"/>
Zip / Postal Code:	<input type="text"/>
Subject Phone #:	<input type="text"/>
Subject Email:	<input type="text"/>
Requested Delivery (AM or PM):	<input type="text"/>

Number Of Kits: 5

Numbered Supply:

100134	100135	100136	100137	100138
--------	--------	--------	--------	--------

Non-Numbered Supply:

Label Lot Number:

Quantity:

Prescriber Sign-off:

Signature	Print Name	Company and Position	Date

Steps to Take:

1. Print the Form
2. Complete the Subject Demographic Fields (name, address, phone, email)
3. Sign and Date the Form
4. Email the completed form to: directtopatient@alamacgroup.com

Edit Subject Data

From the **Subject Events** page, you are able to **Edit** the date associated with an event. Click on **Save** once changes are made.

Subject Events		Kit Assignment History
Click on completed event to view.		
Event	Target Date	Event Date
Registration		14-Apr-2023
Drug Dispensing Event 2		14-Apr-2023
Drug Dispensing Event 3		Skipped
Study Complete		14-Apr-2023

Event	What can be edited
Registration Visit	Visit Date
Drug Dispensing Visit	Visit Date
Study Complete	Study Complete Date

Simplify™ User Modules: Subject Transactions – Entering Already-Existing Subjects



Site User Simplify™ Transactions – Entering Already-Existing Subjects

Steps to Take:

1. Steps will begin when the subject comes in for his/her next planned visit.
2. Select **Enter New Subject** from the **Dashboard**/Home page or from the **Subjects** menu.
3. Enter the subject / Registration details.
 - Randomization Date should be the date of Randomization from REDCap.
 - Follow the normal Registration steps.
 - You must still complete the **Shipment Confirmation Form**, as the Kits assigned will be allocated to the current visit.
4. Go to the newly Registered Subject – **View Existing Subjects** from Dashboard or **Subjects** menu.
5. Catching up to Subject's Visit Schedule
 - If the subject is coming in for his/her **Drug Dispensing Event 2** visit:
 - Select **Skip** and follow the steps to Skip a visit.
 - If the subject is coming in for his/her **Drug Dispensing Event 3** visit:
 - You will SKIP the next TWO visits, so the Skip Visit steps will be followed two times.

Site User Simplify™ Transactions – Entering Already-Existing Subjects

1

Register Subject

All information is required. *

Registration Details

Subject ID *:

Date of Birth *:

Randomization Date *:

Is Subject Physically at the Site? *

☐ Yes - subject is physically at site for dispensing

☒ No - supply will be shipped from depot to subject location

Will supplies be dispensed from site inventory at the next scheduled visit? *

☐ Yes - subject will be at site

☒ No - supply must be shipped from depot to subject location

2

Subjects ▶ Subject CHGAF-4004-9996 (In Treatment)
US 1, USA (4004)

Subject Data

Randomization Date: 11/7/2022
Date of Birth: 01-Jan-1969
Site Code: 4004

Next Event: Drug Dispensing Event 2

3

Event	Target Date	Event Date	
Registration		14-Apr-2023	<input type="button" value="Edit"/>
Drug Dispensing Event 2		Skipped	<input type="button" value="Edit"/>
Drug Dispensing Event 3	10-Dec-2023		

Simplify™ – Administrative Tasks

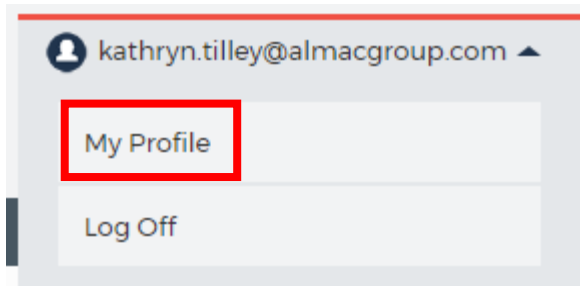


My Profile – Basic Details

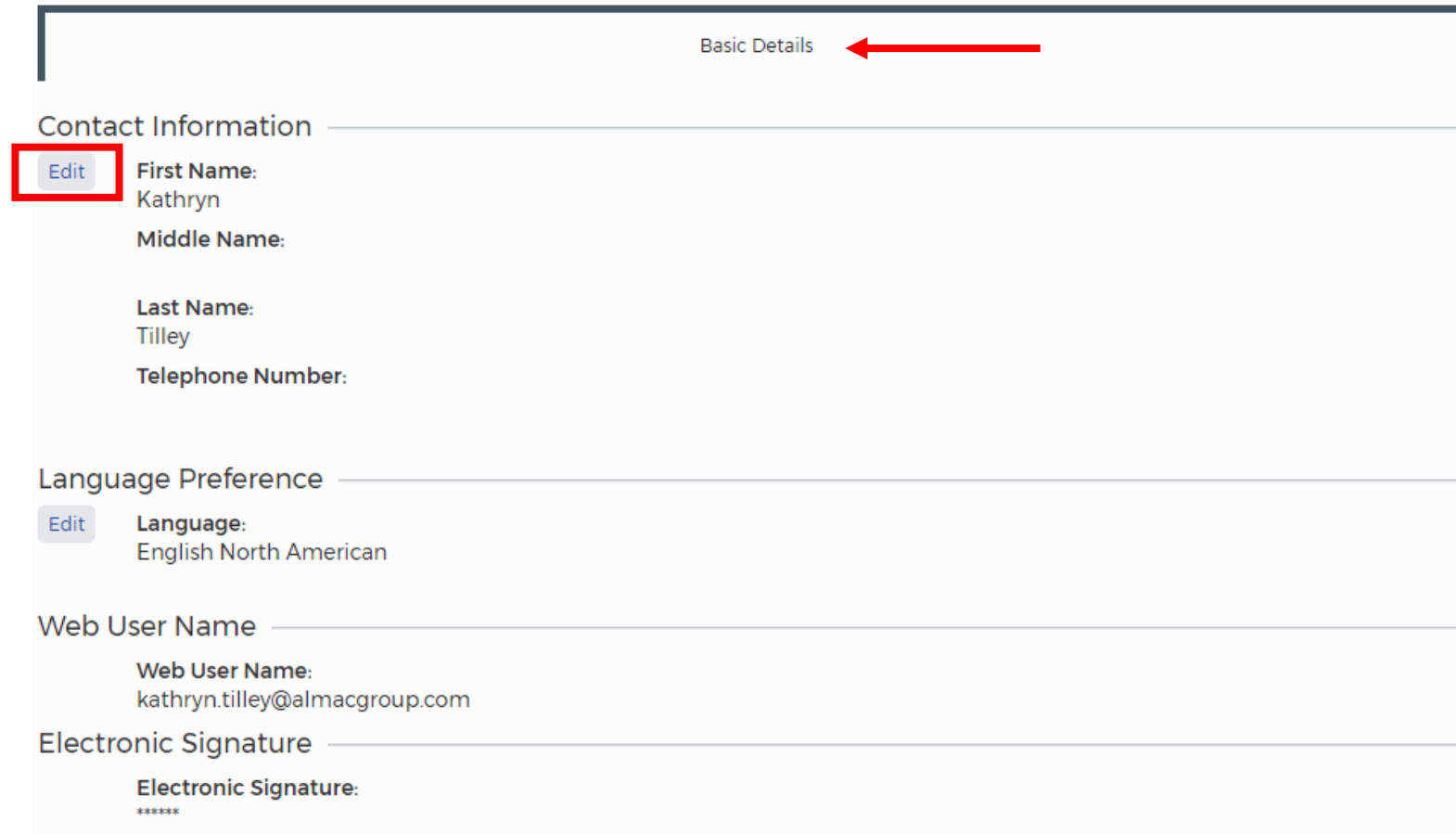
From the upper right-hand corner, click on the arrow next to your email address.

Select **My Profile**. Select the **Basic Details** tab.

Click on **Edit** next to the **First Name** field to update **Name** and **Telephone Number**.



NOTE: For Language Preference, the only option is English

A screenshot of the 'Basic Details' profile page. At the top right, the text 'Basic Details' is displayed with a red arrow pointing to it from the left. The page is divided into sections: 'Contact Information', 'Language Preference', 'Web User Name', and 'Electronic Signature'. Each section has an 'Edit' button. The 'Contact Information' section shows 'First Name: Kathryn', 'Middle Name:', 'Last Name: Tilley', and 'Telephone Number:'. The 'Language Preference' section shows 'Language: English North American'. The 'Web User Name' section shows 'Web User Name: kathryn.tilley@almacgroup.com'. The 'Electronic Signature' section shows 'Electronic Signature: *****'. The 'Edit' button for the 'First Name' field is highlighted with a red rectangular box.

My Profile – Alert Subscriptions

Select the Alert Subscriptions tab to update which alerts you do/do not wish to receive.
Click on Edit under Alert Subscriptions; check the corresponding boxes; click on Save.

My Profile

Basic Details

Alert Subscriptions

Alert Subscriptions

Checking an alert will ensure you will receive it.

 denotes an Unblinding alert

Edit

NOTE: Alerts may vary based on user role in the IXRS.

Subject Discontinued From Study Alert

Subject Registered at Site Alert

Subject Kit Assignment Alert

Subject Missed Visit Alert


Subject Transaction Voided Alert

Subject Visit Marked as Not Registered Alert

Subject Visit Registered Outside of Visit Window Alert

Subject Visit Voided Alert

 Supply Release Approval Needed Alert - UNBLINDED

 Supply Release Approved or Rejected Alert - UNBLINDED

Supply Shipment Alert

Unconfirmed Shipment Alert

☐
☒
☒
☒
☐
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☐

Checkmarks indicate that the alert will be received as applicable.

Cancel

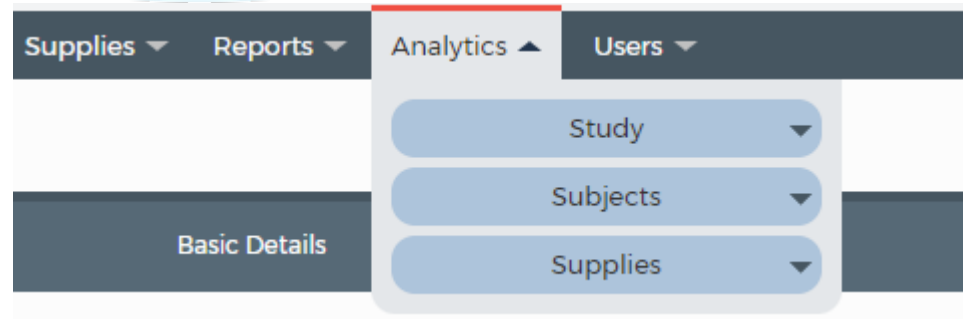
Save



Simplify™

Analytics – Study/Subjects/Supplies

From the **Analytics** menu, select the type of Report to view (Study, Subjects, Supplies).



Study Reports

- Registration Summary
- Site Details

Subjects Reports

- Subject Details
- Visit Details

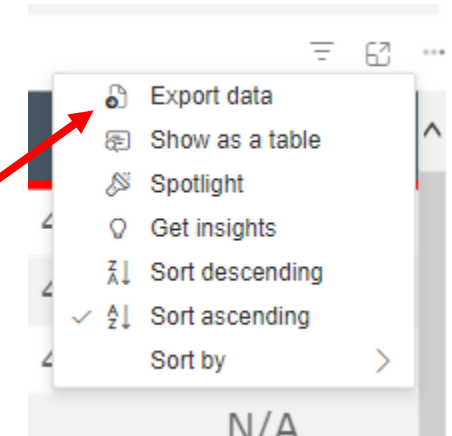
Supplies Reports

- Shipment Details

SAMPLE

Visit Details

Country	Site Code	Investigator	Subject ID						
All	All	All	All						
Returning 42 records									
Country	Site Code	Site Name	Investigator	Subject ID	Randomization Number	Cohort	Subject Status	Treatment Arm	Visit Number
United States	4004	US 1	First name Last name	CHGAF-4004-0001	N/A	N/A	In Treatment	A : Multaq (Dronedarone) 400 mg	1
United States	4004	US 1	First name Last name	CHGAF-4004-0001	N/A	N/A	In Treatment	A : Multaq (Dronedarone) 400 mg	2
United States	4004	US 1	First name Last name	CHGAF-4004-0001	N/A	N/A	In Treatment	A : Multaq (Dronedarone) 400 mg	3
United States	4004	US 1	First name Last name	CHGAF-4004-0001	N/A	N/A	Study Complete	N/A	N/A
United States	4004	US 1	First name Last name	CHGAF-4004-0002	N/A	N/A	In Treatment	A : Multaq (Dronedarone) 400 mg	1
United States	4004	US 1	First name Last name	CHGAF-4004-0002	N/A	N/A	In Treatment	A : Multaq (Dronedarone) 400 mg	2
United States	4004	US 1	First name Last name	CHGAF-4004-0002	N/A	N/A	In Treatment	A : Multaq (Dronedarone) 400 mg	3
United States	4004	US 1	First name Last name	CHGAF-4004-0002	N/A	N/A	Study Complete	N/A	N/A
United States	4004	US 1	First name Last name	CHGAF-4004-0003	N/A	N/A	In Treatment	A : Multaq (Dronedarone) 400 mg	1

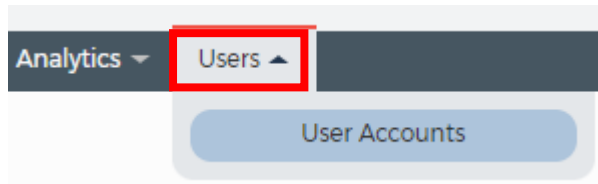


Users – User Accounts

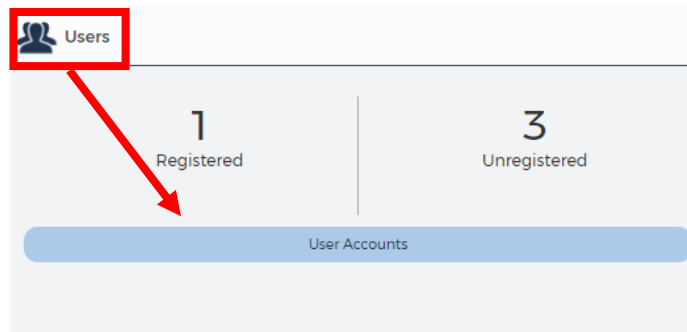
From the **Users** menu, select **User Accounts** OR from the *Dashboard* select **User Accounts**.

Available Options:

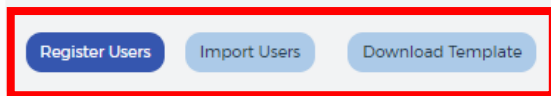
- Add new user (Register)
- Import Users
- Download Template – use for importing a larger number of users at one time
- Search for user – to edit, update role(s), deactivate



OR



User Accounts



Last Name:	Email Address:	Status:	Created Date (UTC):	Unblinding Status:	Roles:	Sites:	Depots:	
<input type="text"/>	<input type="text"/>	<input type="text" value="All"/>	<input type="text" value="DD MMM YYYY"/>	<input type="text" value="All"/>	<input type="text" value="All"/>	<input type="text" value="4004, Title First name Las"/>	<input type="text" value="All"/>	<input type="button" value="Search"/>

Search

Users – User Accounts: Register New User(s)

After selecting Register Users, select the *Unblinding Status*.

Select the User Role and click on Continue.

Select *Site Access*; when Site(s) is selected, specific sites will display. Select the corresponding site for the user. Click on Continue.

1

User Accounts ▶ Register Users

Select Credentials

One or more users can be added using this feature, as long as the users

Unblinding Status and Role Selection

The following unblinded status and selected role(s) will be assigned to t

Unblinding Status *

- ☐ These users are Blinded
- ☒ These users are Unblinded

Cancel

2

- ☐ Site Investigator ⚠
- ☐ Site Personnel ⚠
- ☐ Sponsor/Admin ⚠

NOTE: When using Register Users, you can only add multiple users at a time only if they share the same unblinding status, role, and site access

3

Site Access

Select access level: Countries or Site(s)

Country level access provides access to all current and futures sites in the
Site level access provides access to those selected site(s) only.

Access Level *

- ☐ Countries
- ☒ Site(s)

Site Selection

United States

- ☒ 1234, John Doe, (Sample Upload)
- ☐ 4004, Title First name Last name, (US 1)
- ☐ 50005, Title First name Last name, (US 2)
- ☐ 600006, Title First name Last name, (US 3)
- ☐ 9999, Bob Jones, (TEST 5)

Users – User Accounts: Register New User(s) (continued)

Enter the User's *Email Address*, *First Name*, and *Last Name*.

Click on Add. The user will appear just above where you enter the user details.

Continue to add users as needed. When all users have been added, click on Review.

Add Users

Email Address	First Name	Middle Name	Last Name
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Add Users

Email Address	First Name	Middle Name	Last Name
kathryn.tilley@gmail.com	Kathryn		Tilley
JohnSmith@noemail.com	John		Smith

Users – User Accounts

Confirm the user(s) being added.

Click on Register Users.

Each user added will receive an email requesting registration.

Email Address	First Name	Middle Name	Last Name
kathryn.tilley@gmail.com	Kathryn		Tilley
JohnSmith@noemail.com	John		Smith

Unblinding Status
Unblinded

Roles
Site Personnel

Country/Site Access
1234, John Doe, (Sample Upload)

Depot Access
N/A

Cancel Previous **Register Users**

Simplify™ User Support




Technical Support

Toll Free Phone (USA): 1-877-738-8831 and press 0

- Country specific toll-free access can be found in the Phone/IVR access link. Users can press '00' to access technical support.
- Email: IRTHelp@almacgroup.com

Within the web Simplify™, users can find Simplify™ Technical Support as follows:

A link to “Technical Support” will appear at the bottom of each page of the web Simplify™ user interface providing the toll-free number and email request form.

On-line help and information on how to contact Support can be found where you see the  icon.

24/7
SUPPORT

Users can contact Almac Technical Support via:

- Phone (local toll-free number)
- Email
- On-line via LiveChat

Being available to you 24/7/365 by various convenient options is important.



Thank You

Questions?



AFib / Contact

Almac Technical Support

Toll Free Phone (USA): 1-877-738-8831 and press 0

Email: IRTHelp@almacgroup.com



Thank You