



CHANGE AFib:

A Pragmatic Randomized Clinical Trial
of Early Dronedarone versus Usual Care to Change and Improve
Outcomes in Persons with First-Detected Atrial Fibrillation

Fireside Chat – May 16, 2023

CHANGE AFib is a collaboration between the American Heart Association and the Duke Clinical Research Institute, with support from Sanofi US Services Inc.



Meeting Reminders



Please Note:

- All participants will be muted upon entry.
- Meeting is being recorded and will be archived on our trial website:
www.changeafib.org

Questions?

- Please hold questions until our Q&A session at the end of the call.
- Feel free to submit questions in the chat throughout the call, knowing they will be addressed during the Q&A session.

If you are having issue with computer audio, please call in using the appropriate number below.

Dial by your location:

+1 (301) 715-8592	(Washington DC)
+1 (312) 626-6799	(Chicago)
+1 (646) 876-9923	(New York)
+1 (253) 215-8782	(Tacoma)
+1 (346) 248-7799	(Houston)
+1 (669) 900-6833	(San Jose)

Meeting ID: 850 5286 4919

Passcode: changeafib



Agenda:



Welcome & Introductions



Investigator Meeting Recap



Trial Progress Update



Protocol Updates & Trial Reminders



Almac Simplify™ IRT Training and Q&A



Overall Q&A and Close



Investigator Meeting Recap

Thank You For Attending!

- We had an amazing turnout and meaningful participation! Approximately 90 individuals from 50 sites across 26 states joined us in DC for a day of learning and great conversation!
- For those unable to attend, please review meeting materials [HERE](#)
- Below is an overview of topics presented on
 - / Background and Rationale for Trial
 - / Protocol V3.0 Review and Drug Provision
 - / ALMAC Simplify IRT Training
 - / Patient Reported Outcomes
 - / Subject Enrollment Strategy Panel
 - / Various Q&A



Pictures From The Day!



TRIAL ENROLLMENT GOAL

2023 Enrollment Goal:

3 SUBJECTS

PER SITE PER MONTH

Thank you to all our CHANGE AFib trial teams on your hard work and dedication!

As the barrier of drug access has been removed, we encourage you to double down on your recruitment efforts to enroll 3 subjects per site per month!





Trial Progress Update

Trial Progress – as of May 16, 2023

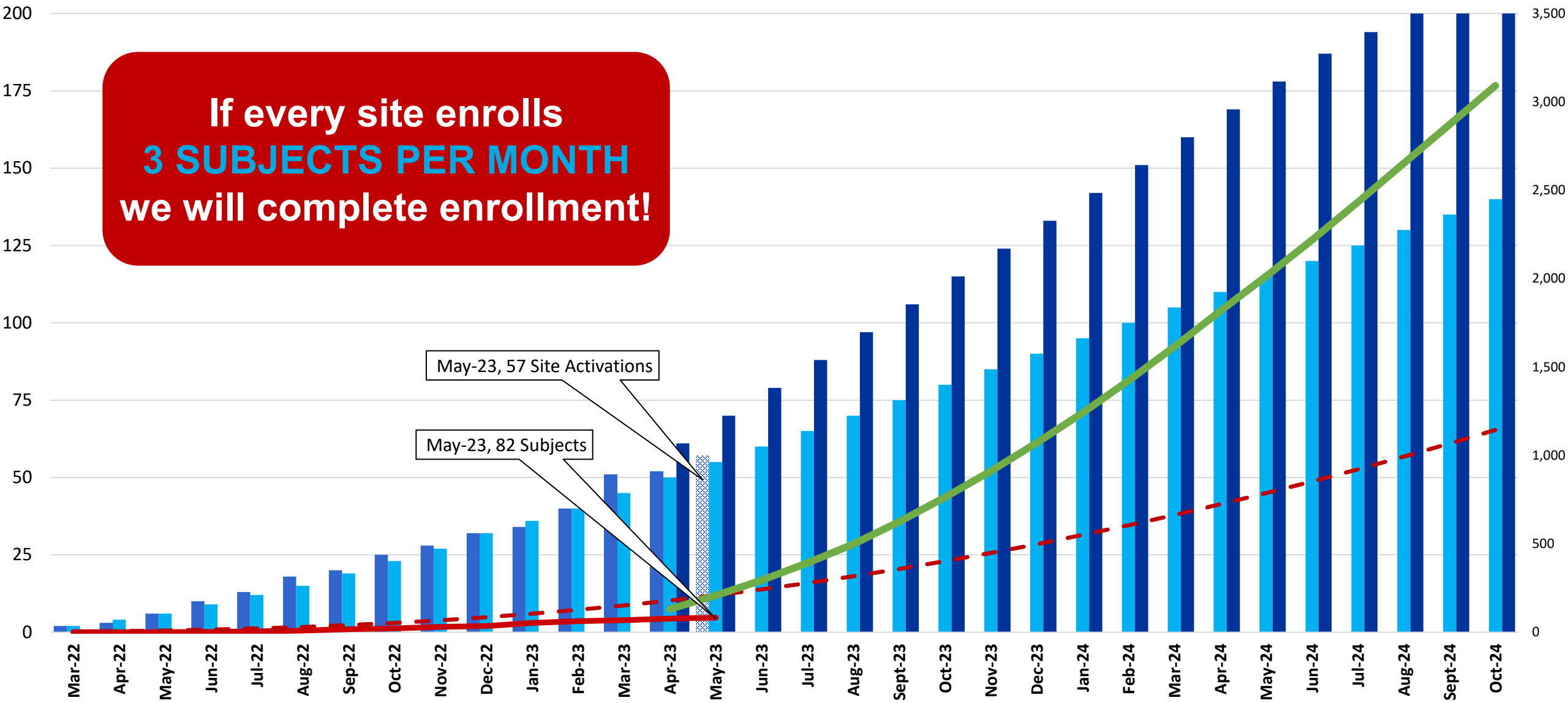
Site Status	Current Status	Trial GOAL!
Subject Enrollments	82	3000
Activated Sites	57	200
Sites in Onboarding	61	-
Sites Assessing Feasibility	42	-

CHANGE AFib Activation & Enrollment Projections

of SITES

of SUBJECTS

**If every site enrolls
3 SUBJECTS PER MONTH
we will complete enrollment!**



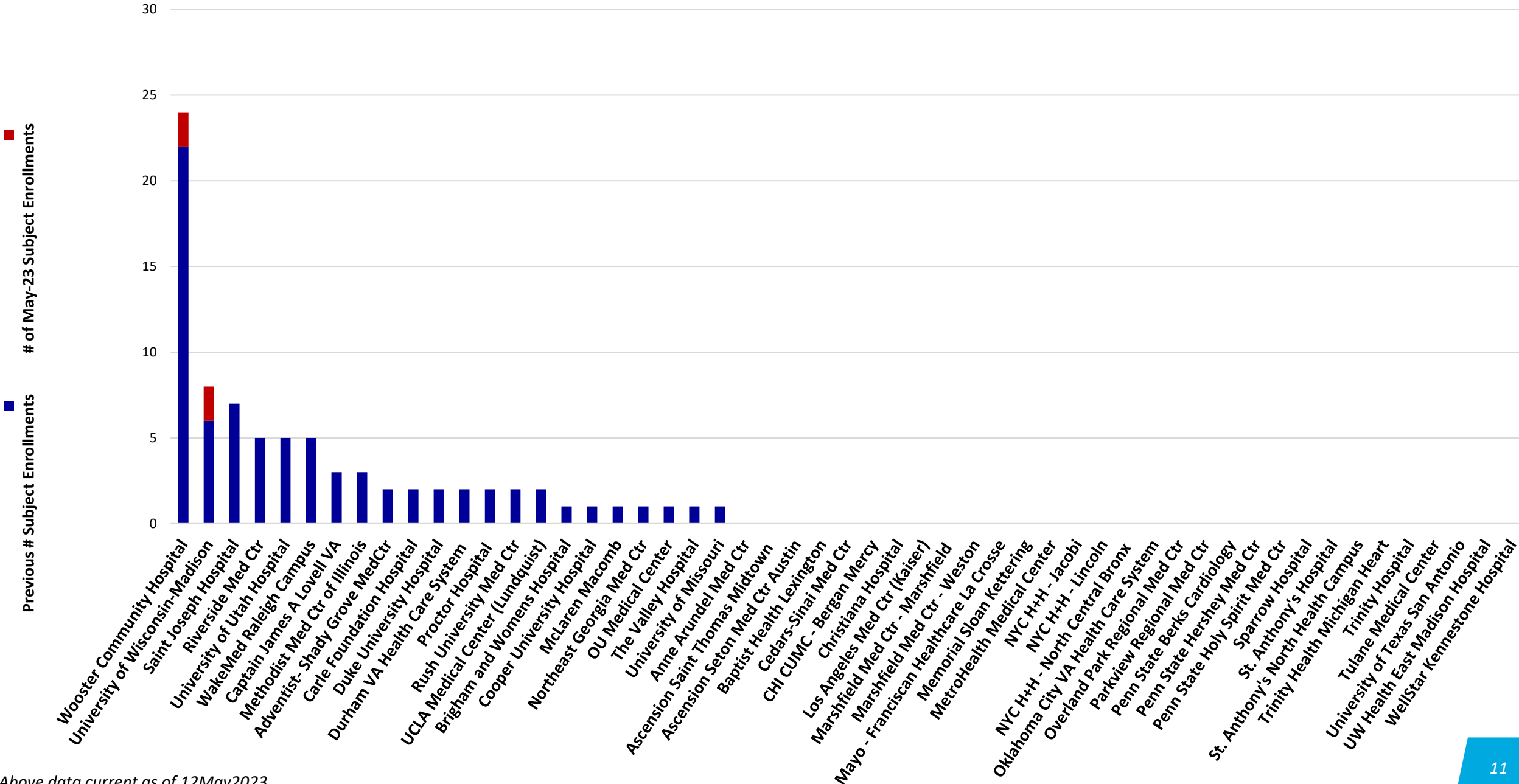
May-23, 57 Site Activations

May-23, 82 Subjects



- ACTUAL Cumulative Site Activations
- Projected Cumulative Site Activations (w/o Drug)
- DRUG - Projected Cumulative Site Activations
- ACTUAL Cumulative Subject Enrollments
- Projected Cumulative Subject Enrollments (w/o Drug)
- DRUG - Projected Cumulative Subject Enrollments

CHANGE AFib 82 Subject Enrollments from 22 Sites

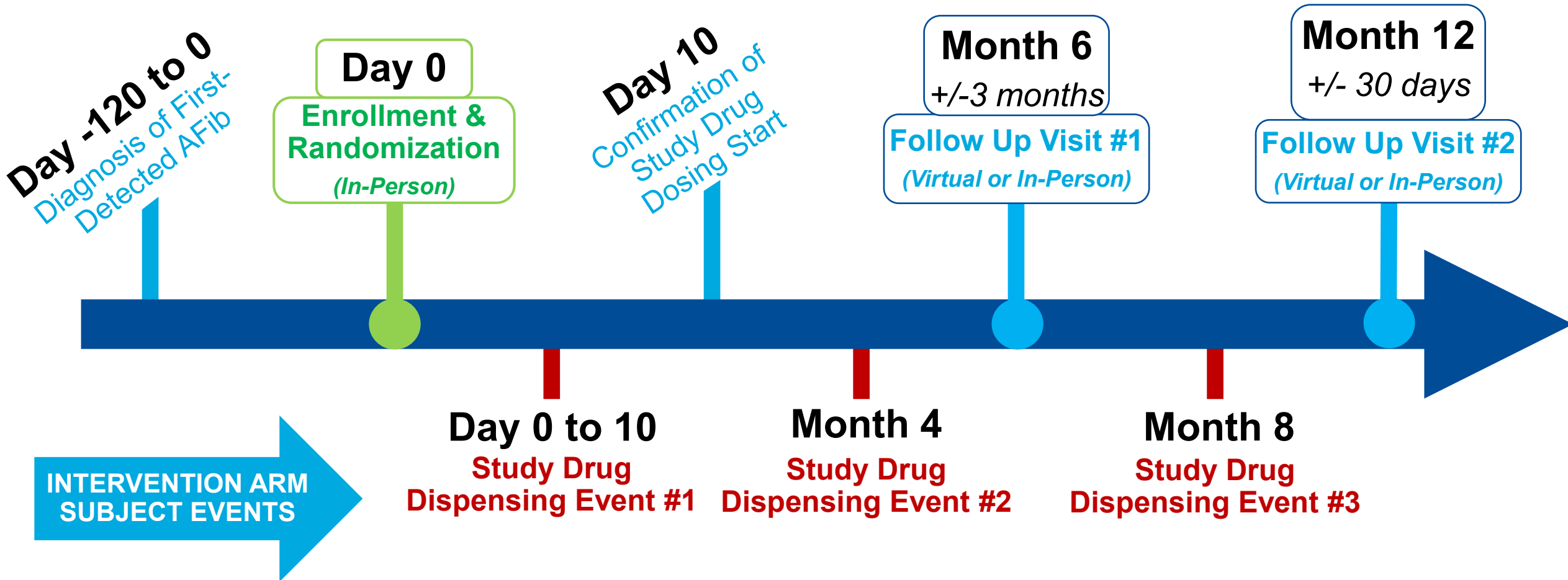


Above data current as of 12May2023



Protocol Updates & Trial Reminders

CHANGE AFib Schedule of Activities



Each study drug kit shipment will cover 4 months of drug supply, with 1 additional 1-month bottle as buffer

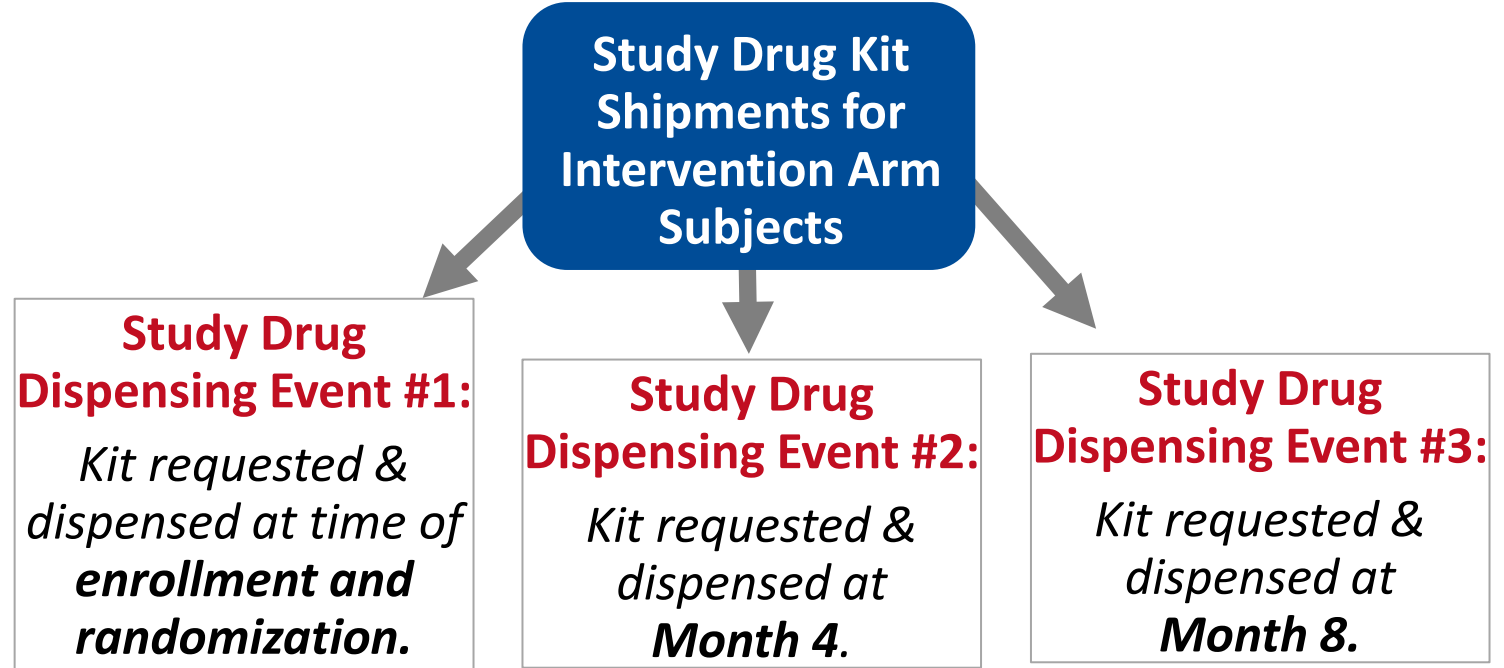
NEW CHANGE AFib *Subject Visit Tracker*

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
	Subject ID # CHGAF-#####	Date of Randomization MM/DD/YYYY	Randomization Assignment	Date of Diagnosis MM/DD/YYYY	Treatment Arm Subjects: On/Off Drug	Drug Shipment #1 (within 10days of Randomization)	Drug Shipment #2 (4months post- randomization)	6Month FU Window Left (-3months)	6Month FU Visit TARGET DATE	6Month FU Window Right (+3months)	Drug Shipment #3 (8months post- randomization)	12Month FU Window Left (-30days)	12Month FU Visit TARGET DATE	12Month FU Window Right (+30days)
1														
2	CHGAF-99999-0001	6/3/2022	Usual Care Alone	8/2/2022	On	6/13/2022	10/1/2022	9/1/2022	11/30/2022	2/28/2023	1/29/2023	5/4/2023	6/3/2023	7/3/2023
3	CHGAF-99999-0002	7/8/2022	Dronedarone	7/20/2022	On	7/18/2022	11/5/2022	10/6/2022	1/4/2023	4/4/2023	3/5/2023	6/8/2023	7/8/2023	8/7/2023
4	CHGAF-99999-0003	7/25/2022	Usual Care Alone	6/23/2022	On	8/4/2022	11/22/2022	10/23/2022	1/21/2023	4/21/2023	3/22/2023	6/25/2023	7/25/2023	8/24/2023
5	CHGAF-99999-0004	7/27/2022	Dronedarone	6/5/2022	Off	8/6/2022	11/24/2022	10/25/2022	1/23/2023	4/23/2023	3/24/2023	6/27/2023	7/27/2023	8/26/2023
6	CHGAF-99999-0005	8/10/2022	Dronedarone	6/16/2022	On	8/20/2022	12/8/2022	11/8/2022	2/6/2023	5/7/2023	4/7/2023	7/11/2023	8/10/2023	9/9/2023
7														
8														
9														
10														
11														
12														

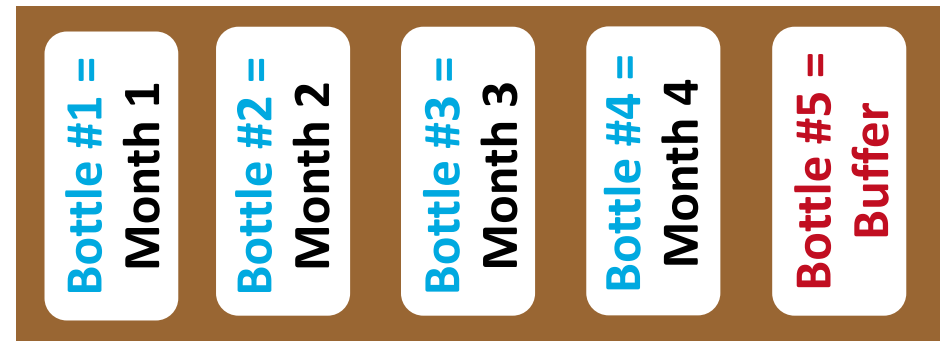
- Aids in Protocol Visit Scheduling and Study Drug Dispensing Event planning.
- Template posted on the trial website.

Study Drug Kit Configuration & Dispensation

- Patients randomized to the intervention (dronedarone) arm will receive 3 study drug kit shipments.
- Each study drug kit shipment will cover 4 months of drug supply, with 1 additional bottle as buffer.
- **NOTE: 1 bottle = 1 month of dronedarone drug supply (60, 400mg tablets)**

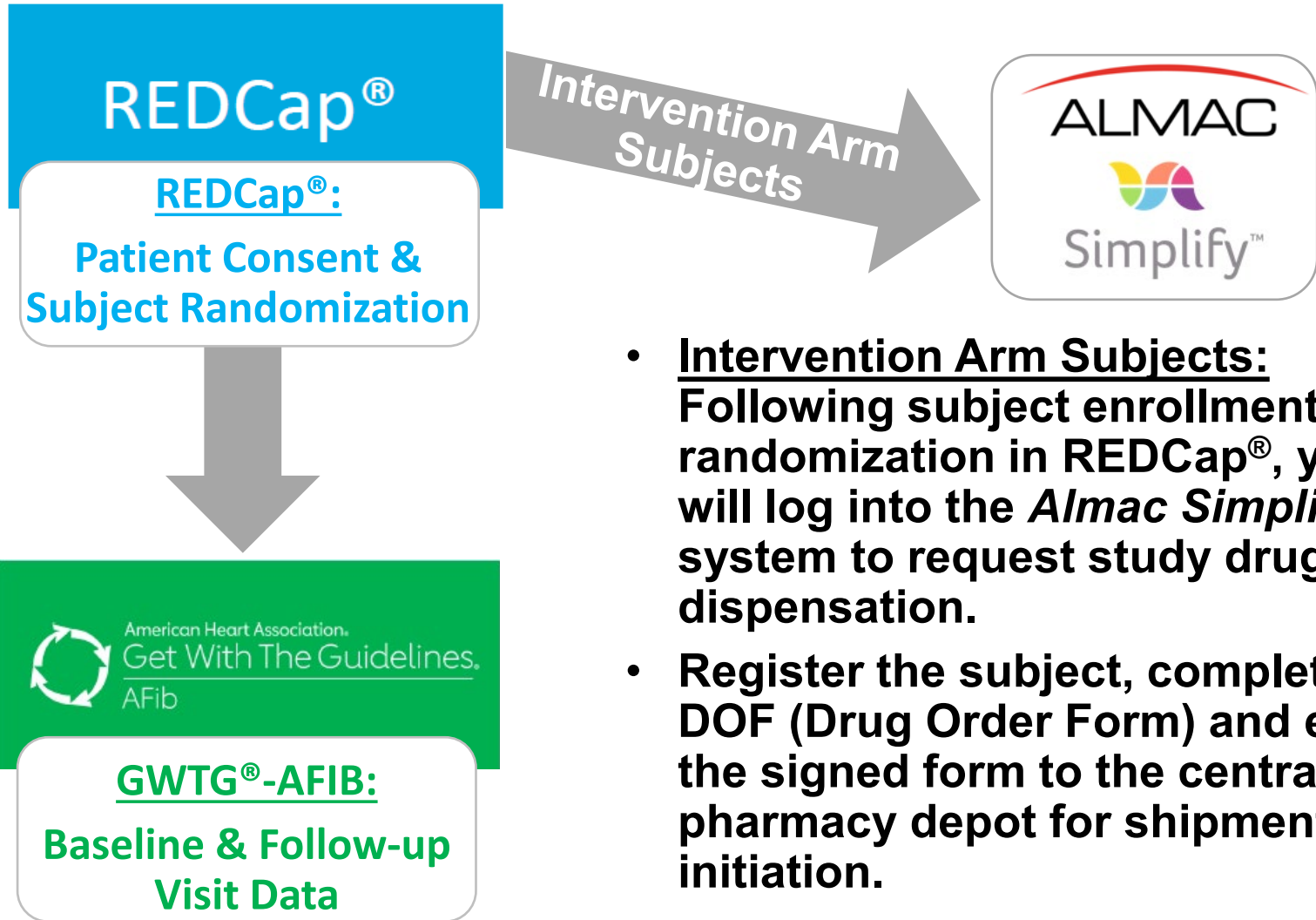


Each Study Drug Kit Shipment will look like this:



Recap of Trial EDC & IRT Systems

- REDCap® remains to be the consent and randomization tool for all CHANGE AFib subjects.



- GWTG®-AFIB remains to be the EDC for all CHANGE AFib subject study visit data (baseline and both follow-up visits).

- **Intervention Arm Subjects:** Following subject enrollment and randomization in REDCap®, your site will log into the *Almac Simplify™* IRT system to request study drug kit dispensation.
- **Register the subject, complete the DOF (Drug Order Form) and email the signed form to the central pharmacy depot for shipment initiation.**

PROTOCOL V4.0: Acute Care Encounter Update

- Under Protocol V4.0, potential subjects are no longer required to have an acute care encounter for the diagnosis of their first-detected Atrial Fibrillation in order to be eligible for trial participation.
 - ✓ *To note, patients seen in the acute care setting (e.g., ER, Obs, Inpatient) where their first-detected AFib is diagnosed are still eligible under Protocol V4.0.*
- While you await IRB Approval for Protocol V4.0, please flag all future eligible subjects that do not have an acute care encounter for their first-detected AFib diagnosis. These patients will be eligible under Protocol V4.0 and can be enrolled within 120 days of their diagnosis.
- **REMINDER: Continue to screen and enroll subjects based on your current IRB approved protocol version. Enrollment following Protocol V4.0 should ONLY be conducted following receipt of your site's formal Protocol V4.0 Activation Notice.**



PROTOCOL V4.0

Summary of Changes

Subject Eligibility Changes:

- **Removal of the *Acute Care Encounter* Inclusion Criteria.**
 - Potential subjects are no longer required to have an acute care encounter for the diagnosis of their first-detected Atrial Fibrillation in order to be eligible for trial participation.
- **Definition of ‘Electrocardiographic documentation of atrial fibrillation’.**
 - Electrocardiographic documentation includes a standard 12 lead electrocardiogram, mobile ECGs, ambulatory monitoring (e.g., Holter), telemetry, or electrograms from cardiac implanted electronic devices (i.e., pacemaker).
- **Removal of Exclusion Criteria #2**
 - Prior hospitalization for atrial fibrillation (other than the qualifying event).



Protocol V4.0 Next Steps

As of 12May2023, Protocol V4.0 has been submitted to the IRB for Master IRB Approval.

- Immediately upon Master Trial IRB Approval receipt, Protocol V4.0 documents will be posted on the trial website to support your Protocol review and IRB submissions. A formal notice will be sent when these documents are available.
- We are anticipating IRB Approval in <2 weeks.

List of Updated Documents:

- Main Study IRB Approval Letter (Date TBD)
- Protocol V4.0 – 12May2023
- Summary of Changes, Protocol V4.0 – 12May2023
- Protocol V4.0 ICF Template & Tracked Changes
- Recruitment Materials – Provider Pocket Cards (*Brochures N/A*)
- Protocol V4.0 Screening Log



Protocol V4.0 IRB Next Steps *Continued*

CENTRAL IRB SITES:

- All trial sites utilizing the Central IRB, Advarra, will automatically be reviewed for approval following the Master Trial Approval.
- IRB approval emails will be sent to each individual site with site-specific approval notices and approved Informed Consent Forms (ICFs).

LOCAL/INSTITUTIONAL IRB SITES:

- All trial sites utilizing their Local/Institutional IRB will be required to submit an IRB Modification.
- Site-Specific ICF edits are required to be sent to CHANGEAFibContracting@heart.org for sponsor approval prior to Local IRB submission.
- If your site has yet to submit to your IRB for the previous modification, please hold off and combine submissions for Protocol V4.0.









Almac Simplify™ IRT Training and Q&A

*Kathryn Tilley, Project Manager
Almac Clinical Services
Central Pharmacy Vendor*

Confidentiality Statement

This presentation contains information that is confidential and proprietary and is not for distribution beyond Almac and/or the client organisation designated on the title slide.

Agenda:

-  Accessing the Almac Simplify™ IRT
-  Adding New Site User Accounts
-  Registering a New Subject
-  Simplify™ User Support

Project Manager

Throughout all project phases
Kathryn Tilley, US/PA

Site Queries

IRTHELP@almacgroup.com



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.

From the AHA:

Upon a site's IRB approval for Protocol V3.0, the AHA trial team will "activate" the site's IXRS access which sends the above registration emails to the PI and Primary Study Coordinator on file.

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>

Login

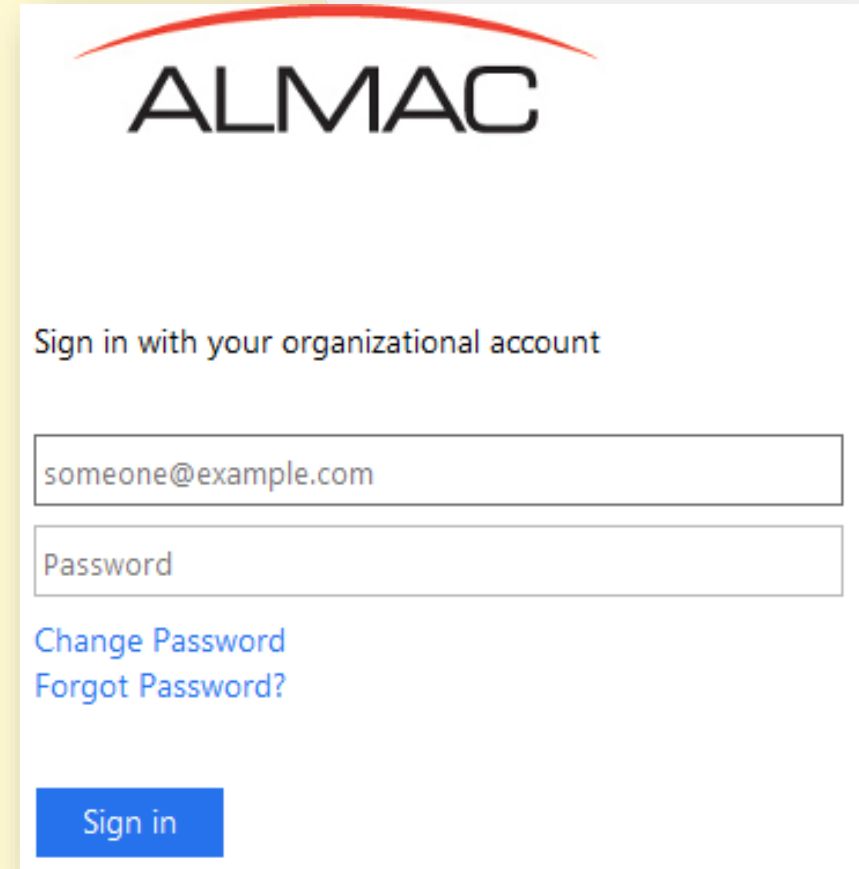


User ID is the user's email address



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

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



The screenshot shows the ALMAC login page. At the top is the ALMAC logo. Below it is the text "Sign in with your organizational account". There are two input fields: the first contains "someone@example.com" and the second is labeled "Password". Below the password field are two links: "Change Password" and "Forgot Password?". At the bottom is a blue "Sign in" button.

Simplify™ Site Dashboard

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.

Menu Bar to select appropriate feature

The screenshot shows the Simplify Site Dashboard interface. At the top is a dark menu bar with the following items: Home, Study, Subjects, Sites, Supplies, Reports, Analytics, and Users. Below the menu bar, the site information is displayed: "US 1, USA (4004) [Active] - Change site". The dashboard is divided into three main sections: 1. **Subjects**: Shows "9 Total Registered" and includes a search input field labeled "Enter Subject ID", a blue "Find Subject" button, and a light blue "Enter New Subject" button. 2. **Supplies**: Shows "0 Available Kits*" and includes a note: "*Kits Available at Site that have... assignable. This count will not include quarantined... part of lots that are 'On Hold for... shipments in transit." A red diagonal banner across this section reads "Not applicable for this study". 3. **Users**: Shows "1 Registered" and "3 Unregistered" and includes a blue "User Accounts" button. A red arrow points from the "User Accounts" button to the text "Shortcut option to select User accounts". Another red arrow points from the "Enter New Subject" button to the text "Shortcut options to select existing subject or create new subject". A third red arrow points from the "Users" section to the text "Menu Bar to select appropriate feature".

Shortcut options to select existing subject or create new subject

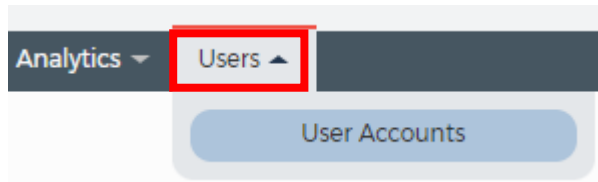
Shortcut option to select User accounts

Users – User Accounts

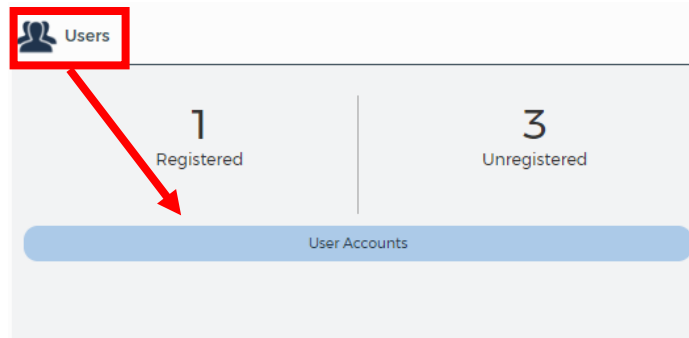
From the **Users** menu, select **User Accounts** OR from the *Dashboard* select **User Accounts**.

Available Options:

- Select 'Register User' to add new member from your study team
- Search for user – to edit, update role(s), deactivate



OR



User Accounts

SEARCH

Register Users

Last Name: Email Address: Status: All Created Date (UTC): DD MMM YYYY Unblinding Status: All Roles: All Sites: 4004, Title First name Last Depots: All

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 lon


Unblinding Status and Role Selection

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

Unblinding Status *


These users are Unblinded


These users are Blinded

 denotes Unblinding

All users are automatically UNBLINDED.

2

Site Investigator 

Site Personnel 

NOTE: When registering users, you can ONLY add multiple users at the same time if they share the same 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

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

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

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

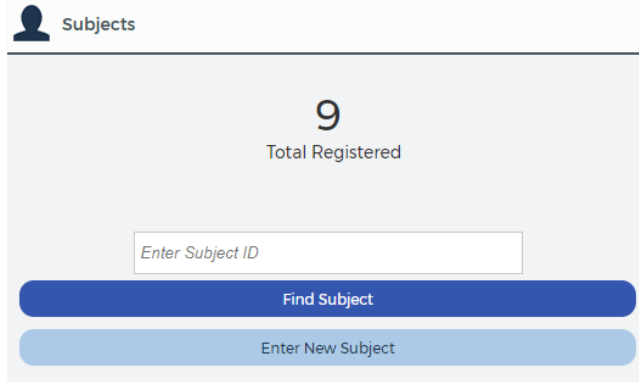
Country/Site Access
1234, John Doe, (Sample Upload)

Depot Access
N/A

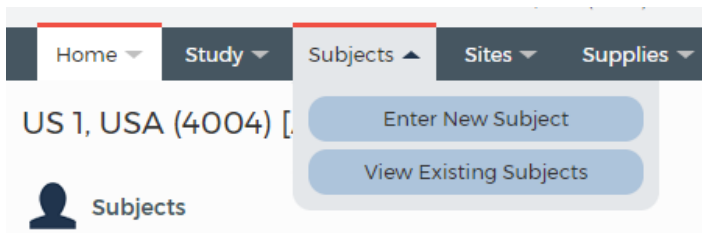
Cancel Previous **Register Users**

Site User Simplify™ Transactions – Registration

Select “*Enter New Subject*” from the Site Dashboard



or “*Enter New Subject*” from the Subjects Menu



AHA RECAP:
Dispensing Event #1 automatically occurs upon Subject Registration in the Almac Simplify™ IRT System.

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 # (4-6 digits) + Subject # (4 digits)
 - ALL Numerical, NO spaces
- Date of Birth – Select YEAR of Birth
- Randomization Date:
 - Date of Randomization in REDCap
 - NOT the date of *Registration* in IRT
- Is Subject Physically at the Site?
 - ALWAYS ANSWER NO for Direct-to-Patient shipping regardless if subject is physically on-site at time of visit.
- 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

DRUG ORDER FORM PROCESS:

Registration is NOT complete until the DRUG ORDER FORM (DOF) is completed, printed and emailed to:

DirectToPatient@almacgroup.com

The DOF is obtained by clicking the ‘Shipment # - Complete Shipment Communication’ button shown in the below screenshot.

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

Click on the Shipment [X] – Complete DOF or DRUG ORDER FORM (aka “Shipment Communication” form) 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)

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

Site User Simplify™ Transactions – Registration (continued)

Drug Order Form (DOF) Completion

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

IXRS Shipment Number: 30 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@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:
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Prescriber Sign-off:

Signature	Print Name	Company and Position	Date
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IMMEDIATE ACTION REQUIRED:

1. Print the Form & Complete DOF

- Complete the DOF electronically with the Subject Demographic Fields (name, address, phone, email). Write in ALL CAPS if completing by hand.

2. Sign, Date and Email the completed DOF to:

directtopatient@almacgroup.com

AHA RECAP:

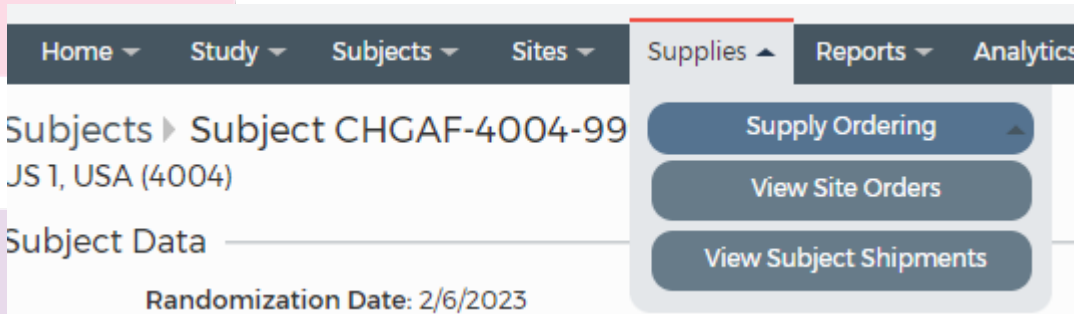
- **Dispensing Event #1 automatically occurs upon Subject Registration in the Almac Simplify™ IRT System.**
- **DOF must be sent within 72hrs of visit registration or drug order will be canceled.**

What to do if you forgot to download the Drug Order Form (DOF):

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:

DD MMM YYYY

To:

DD MMM YYYY

Origin:

All

Fewer search options

Search

What to do if you forgot to download the Drug Order Form (DOF):

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)		

1 **2** 3 Next

Shipment Details include:

- Shipment
- Origin and Destination
- Additional Details
- Contents

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			

What to do if you forgot to download the Drug Order Form (DOF):

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
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Non-Numbered Supply:

Label Lot Number:	Quantity:
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Prescriber Sign-off:

Signature	Print Name	Company and Position	Date

Steps to Take:

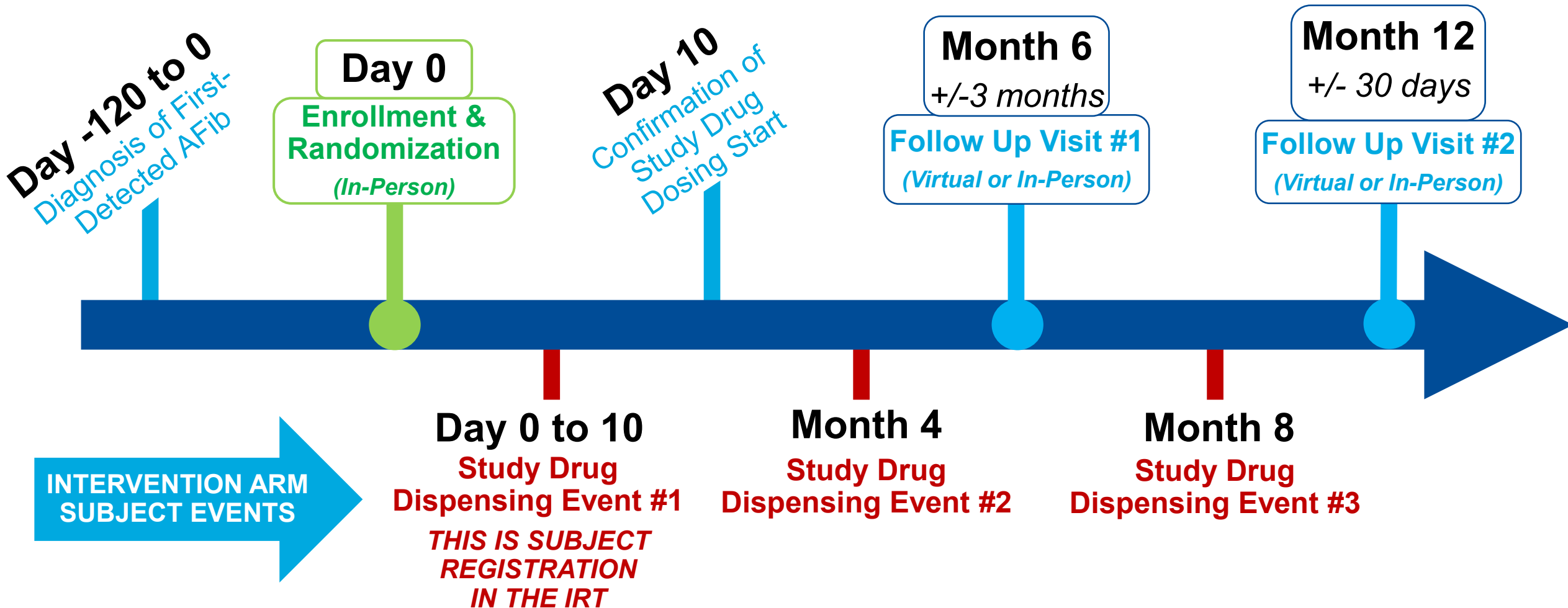
1. Print the Form
2. Complete the Subject Demographic Fields (name, address, phone, email)
3. Sign and Date the Form
4. Email the completed form to: directtopatient@alamacgroup.com

IMPORTANT!

How to Ensure Your Subject Receives Their Study Drug Shipment:

1. Email fully completed DOFs to: directtopatient@almacgroup.com WITHIN 72 HRS
 - *Incomplete or illegible DOFs cause shipment delays! Typing info in CAPS helps!*
 - *Drug order will be canceled if DOF is not received within 72hrs!*
2. EDUCATE YOUR SUBJECTS on the following:
 - Subject will receive shipment 5-7 business days following DOF submission
 - The subject MUST be home to sign for shipment (a surrogate can not sign)
 - Courier can NOT share the below with the subject:
 - That the package is for a clinical trial
 - That the shipment contains medications
 - The trial name
 - **Please reinforce this information so your subjects do not refuse the deliveries!**
 - *Refused deliveries cause major delays and lapse in study drug treatment!*

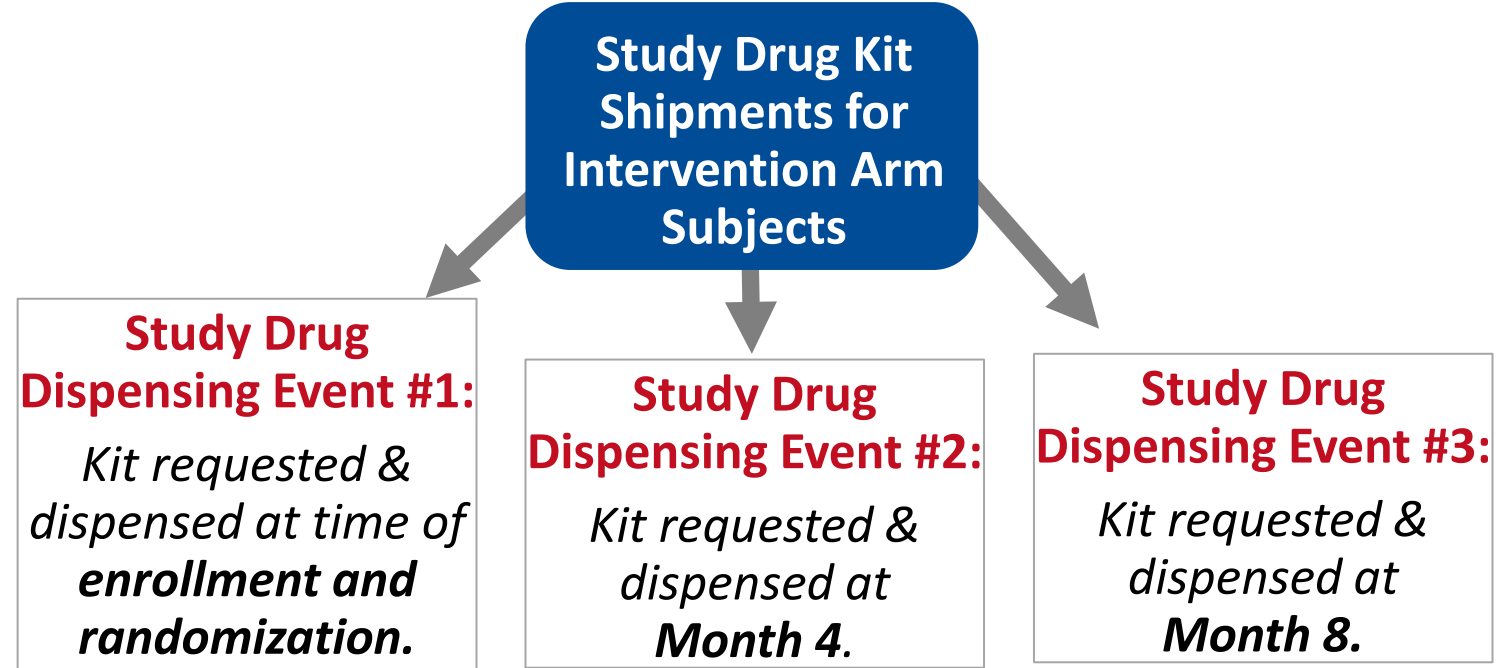
AHA RECAP: CHANGE AFib Schedule of Activities



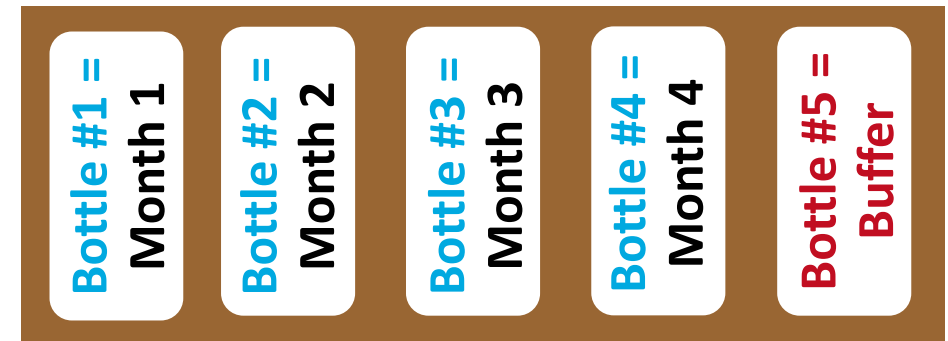
Each study drug kit shipment will cover 4 months of drug supply, with 1 additional 1-month bottle as buffer

AHA RECAP: Study Drug Kit Configuration & Dispensation

- Patients randomized to the intervention (dronedarone) arm will receive 3 study drug kit shipments.
- Each study drug kit shipment will cover 4 months of drug supply, with 1 additional bottle as buffer.
- **NOTE: 1 bottle = 1 month of dronedarone drug supply (60, 400mg tablets)**



Each Study Drug Kit Shipment will look like this:




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.



Top FAQs

Should ALL subjects be registered in Almac Simplify™ IRT ?

- **NO.**
- **ONLY Intervention Arm Subjects** are registered in Almac Simplify™ IRT for study drug dispensation and shipping.

Reminder: Subjects are NOT automatically entered into the Almac Simplify™ IRT System. This must be done by the study team.



I just randomized a subject to the intervention arm. When should I register the subject in Almac Simplify™ IRT?

- Day 0 = Enrollment and Randomization
- Upon randomization, 'register' the subject in Almac Simplify™ IRT and request Dispensing Event #1. Study drug dosing must be initiated within 10 days of randomization.

REMEMBER! With every dispensing event request, a Drug Order Form (DOF) must be completed, signed and dated by the prescribing study team member and emailed back to Almac within 72hours of visit registration.

Reminder: *Study drug shipments take approximately 5-7 business day to complete delivery.*

Is a physical or electronic prescription required for the study drug?

- The study drug prescription for CHANGE AFib is now conducted via the Drug Order Form (DOF) for the trial purposes.
- If your site has other specific requirements (i.e., EMR recording of medications) that are required, please follow those institutional policies.



Does the Site PI Need to Prescribe Dronedarone for the Entire 12 Month Follow-up Period?

- No, the PI **OR** any other prescribing member of trial team member may prescribe the study drug.
- The PI should assume overall responsibility for the subject, their participation and protocol adherence.
- Once subject is randomized to the intervention arm, the study team will log into the Almac Simplify™ IRT system to request a study drug kit shipment be mailed to them.
 - ✓ A DOF (Drug Order Form) is completed, signed by the prescribing trial team member, and emailed to the central pharmacy depot to initiate the study drug shipment.





Almac Q&A



AFib / Thank you & Contact Info

Almac Technical Support

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

Email: IRTHelp@almacgroup.com



Overall Q&A & Close

Trial Payments: Please Submit Your Invoices!

- Trial sites are responsible for submitting invoices for **ALL TRIAL ACTIVITIES**
 - ✓ Invoiceable trial activities include:
 - Site Start-Up Payments
 - Site Incentive Payments (if applicable)
 - Subject Visits
 - Screening Log Payments
- Sites are instructed to submit their invoices to CHANGEAFibInvoicing@heart.org on a quarterly basis for all trial related activities (listed above).
- Trial Invoice Documentation Template can be found on the [‘Resources for Participating Hospitals’](#) page of our trial website.



Mark Your Calendars!

Upcoming Fireside Chats:



Monday, June 12th @ 12-1pm ET

Stay tuned for Summer 2023 dates

Next Up

**Archived webinar recordings & handouts
can be found [HERE](#) on the trial website.*

Meet us in NOLA at HRS!

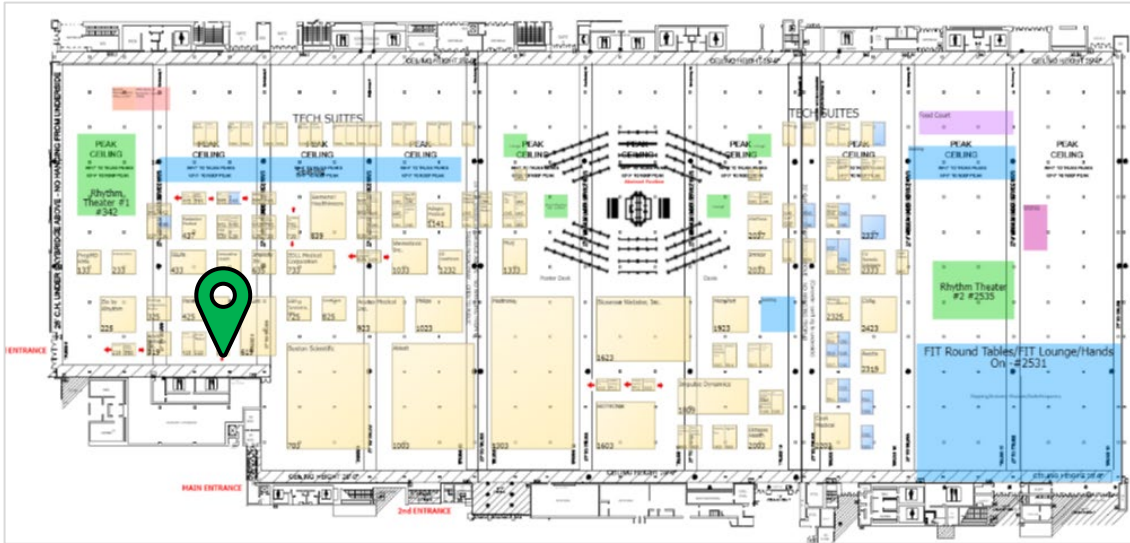
Heart Rhythm 2023

New Orleans, LA | May 19-21, 2023



Visit us at **Booth #519:**

Staff are present to assist with trial questions and help prospective sites complete a site survey.



Meet & Greet with Dr. Piccini and AHA Trial Team:

6:30 – 7:30pm CT

[Ace Hotel - Lobby Bar](#)

600 Carondelet St, New Orleans, LA 70130

(504) 900-1180



RECAP: Key Trial Contacts

General Trial Questions	Email your AHA trial site manager <i>OR</i> If you are a new site, email CHANGEAFib@heart.org
Invoicing Questions	CHANGEAFibInvoicing@heart.org
Contracting Questions	CHANGEAFibContracting@heart.org
Patient Consent & Randomization Questions	CHANGEAF@duke.edu or Tel: 919-668-9339
GWTG[®]-AFIB Questions <i>(GWTG[®]-AFIB is the trial EDC)</i>	Email your AHA trial site manager, <i>OR</i> If you are a new site, email CHANGEAFib@heart.org
sIRB Questions	CIRBI@advarra.com
AE Reporting	CL-CPV-Receipt@sanofi.com Fax Number <i>(to be used in the event e-mail failed)</i> : +33 1 6049 7070
ALMAC IRT Questions	irthelp@almacgroup.com OR 1-877-738-8831 and press '0

A detailed list of key trial contacts can continue to be found [HERE](#) on the trial website

Thank you & Connect With Us!

How to reach the CHANGE AFib Team



AHA Site Managers:

Crystal.Glodek@heart.org

Jack.Goldberg@heart.org

Mariel.Dronson@heart.org



ChangeAFib@heart.org

Resources to Remember



For important trial information and today's meeting recording, go to the **Resources** page at www.changeafib.org or visit the QR Code to the left.

