



Next Steps & Close

Jonathan Piccini, MD, MHS, FACC, FAHA, FHRS
CHANGE AFib Principal Investigator

Samantha Johnson, MPH
CHANGE AFib Trial Director, National Director Clinical Studies, AHA

Disclosures

- Jon Piccini Disclosure:

R01AG074185 from the National Institutes of Aging. Grants for clinical research from Abbott, American Heart Association, Association for the Advancement of Medical Instrumentation, Bayer, Boston Scientific, iRhythm, and Philips. Consultant to Abbott, Abbvie, Abiomed, Altathera, Biotronik, Boston Scientific, Bristol Myers Squibb, LivaNova, Medtronic, ElectroPhysiology Frontiers, Pfizer, Sanofi, Philips, and Up-to-Date.

- Samantha Johnson Disclosure:

Employed by AHA/CHANGE AFib





Key Objective

1. Conclusions & Take-homes from Dr. Piccini
2. Meeting Reminders
3. Tools & Best Practices to Increase Enrollment



Conclusions & Take Homes from Dr. Piccini

REMINDER:

Protocol V3.0 Next Steps

- **Protocol V3.0 has received Master Trial IRB Approval on 22Mar2023.**
- 70% of all Activated Sites have been IRB approved and activated for Protocol V3.0 via the AHA Formal Site Notification.
- Enrollment following Protocol V3.0 should ONLY be conducted following receipt of your site's formal Protocol V3.0 Activation Notice from the AHA.
- **Local/Institutional IRB Sites:**
 - / All trial sites utilizing their Local/Institutional IRB will be required to submit an IRB Modification.
 - / Please send any ICF edits to CHANGEAFibContracting@heart.org for sponsor review and approval prior to Local IRB submission.

Stay tuned for Protocol V4.0 COMING SOON!

REGISTER Intervention Arm Subjects!

- All existing intervention arm subjects will be provided study drug!
- Please register all subjects previously randomized to the intervention arm into the Almac Simplify™ IRT system for study drug provision ASAP!
- Determine where in the 12-mo study timeline these subjects are in order to calculate which study drug dispensing event (3 events) should be ordered.
- SKIP the appropriate dispensing events in the Almac Simplify™ IRT system. Remember, the 'Registration Visit' cannot be skipped.



Mark Your Calendars!



Almac Simplify™ IRT Training

May 16, 2023 @ 1pm ET



Upcoming Fireside Chats

Monday, June 12th @ 12-1pm ET



TRIAL ENROLLMENT GOAL

2023 YEAR END GOAL:
3 SUBJECTS PER SITE PER MONTH

Considering the recent Protocol V3.0 approval and study drug provision, in addition to continually activating new trial sites, we know can meet this 2023 goal together!

Please meet with your CHANGE AFib trial team to strategize improved screening and enrollment tactics accounting for all recent and exciting trial updates!



Meeting Resources:

- All materials from today will be posted to our trial website: CHANGEAFib.org
- Please share today's information with your colleagues.
- CHANGEAFib.org → Resources → Resources for Participating Hospitals
Password: change2021!



Protected: Resources for Participating Hospitals

/ APRIL 10, 2023

These are selected resources for participating hospitals.

Training

- [Instructions for online training module](#)
- [Online training module](#)
- [Online training module slides](#)
- [Electronic Data Collection Systems Overview Handouts](#)

Trial FAQ, Newsletters, & Fireside Chats

- [FAQ](#)
- [Newsletters](#)
- [Fireside Chat Recordings and Handouts](#)

IRB Information and Documents

- [Resources to support IRB submission](#)

Screening, Enrollment, and Randomization

Meet us in NOLA at HRS!

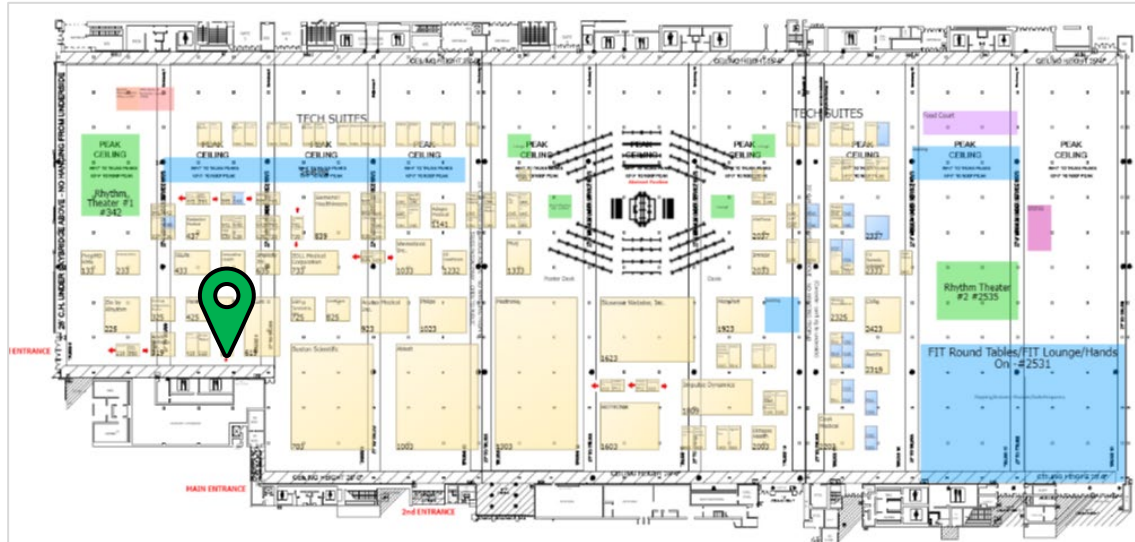
Heart Rhythm 2023

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:

Be on the lookout for more details on how we can connect!



Travel Information:

- Please review previously provided *AHA Volunteer and Expense Guidelines* for travel policies. Materials are also on the USB in your giftbag.
- **By Tues, May 9th**, send expense Excel doc and receipt PDF to CHANGEAFib@heart.org
- For travel assistance, contact:
AHA's Travel Desk – World Travel
1-800-251-9047
greenteam@worldtrav.com
- For those driving, the front desk will validate your parking.



Key Trial Contacts

! IMPORTANT TRIAL CONTACTS !

General Trial Questions	CHANGEAFib@heart.org
AHA Site Managers	<ul style="list-style-type: none">• Crystal.Glodek@heart.org• Jack.Goldberg@heart.org• Maribel.Dronson@heart.org
REDCap Questions	CHANGEAF@duke.edu or (919) 668-9339
Almac Simplify™ IRT Questions	IRTHelp@almacgroup.com or 1-877-738-8831
GWTG-AFib (Trial EDC) Questions	AHA Site Managers or CHANGEAFib@heart.org
Contracting Questions	CHANGEAFibContracting@heart.org
Invoicing Questions	CHANGEAFibInvoicing@heart.org
Adverse Event Reporting	Sanofi PV at CL-CPV-Receipt@sanofi.com



AFib / Contact

Jonathan Piccini, MD, MHS, FACC, FAHA, FHRS
CHANGE AFib Principal Investigator

jonathan.piccini@duke.edu

Samantha Johnson, MPH
CHANGE AFib Trial Director

Samantha.Johnson@heart.org



Thank You and Safe Travels Home!

**We look forward to
CHANGING AFib with you all!**