Afternoon Q&A Session

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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, Ablacon, Altathera, Biotronik, Boston Scientific, Bristol Myers Squibb, LivaNova, Medtronic, ElectroPhysiology Frontiers, Pfizer, Sanofi, Philips, and Up-to-Date.

- Sean Pokorney Disclosure:

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- Samantha Johnson Disclosure:

  Employed by AHA/CHANGE AFib

- Devin Keating Disclosure:

  Employed by AHA/CHANGE AFib

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Is Dronedarone Being Provided by the Trial?

- **YES!** Dronedarone will be provided to all subjects randomized to the intervention arm, including those previously enrolled and future enrollments.
  - This update is reflected in the most recent Protocol V3.0 amendment being rolled out.
  - We're utilizing a direct-to-patient shipment method via the Central Pharmacy, *Almac Clinical Services (no on-site pharmacy support is needed).*
  - **Please await formal activation notice from AHA sponsor team prior to enrolling under Protocol V3.0 and continue to enroll under Protocol V2.0.**

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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.

CHANGE AFib / PI: Principal Investigator

Should ALL subjects be registered in Almac Simplify™ IRT ?

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

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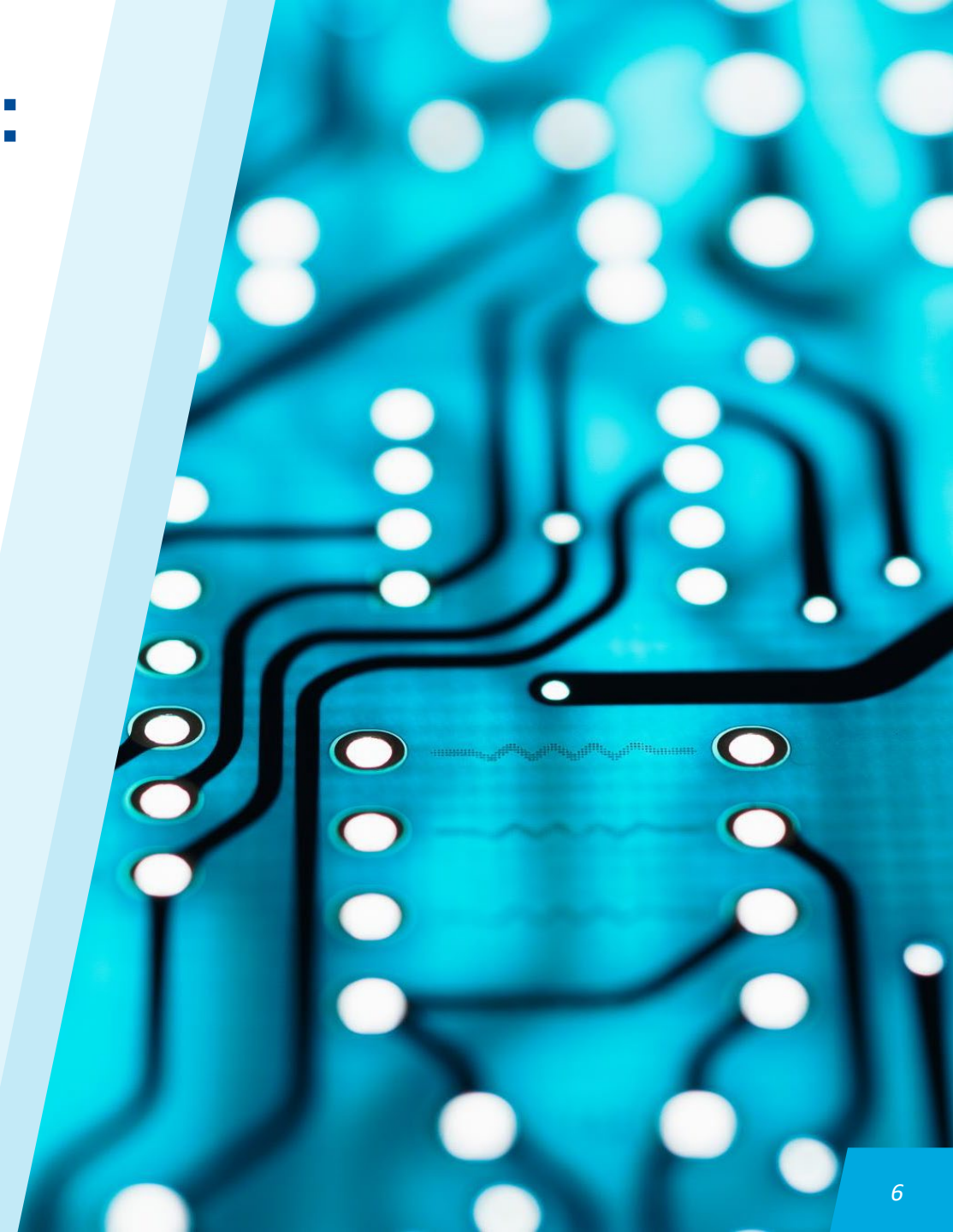
What Trial System do I use to:
Consent?
Randomize a Subject?
Request a Study Drug Kit?
Enter Visit Data?

- **REDCap®** serves as the consent and randomization tool for ***ALL*** CHANGE AFib subjects.
- **GWTG®-AFib** is the EDC for study visit data for ***ALL*** CHANGE AFib subjects.
- The **Almac Simplify™ IRT** system is the Drug Order & Dispensation system for ***intervention arm subjects.***



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

- Day 0 = Enrollment and Randomization
- Within 10 days of randomization, ‘register’ the subject in Almac Simplify™ IRT and request Dispensing Event #1.

REMEMBER! With every dispensing event request, a Drug Order Form (DOF) must be printed out *(in ALL CAPS)*, filled out, signed by the prescribing study team member and emailed back to Almac in order to initiate the shipment.

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How do existing subjects get study drug kits? Which kit should I request?

- Existing intervention arm subjects will be provided study drug. However, they do NOT need the full supply of study drug. Therefore, 'skipping' events in the Almac Simplify™ IRT system will be required.
- 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.
- The 'Registration Visit' cannot be skipped in the Almac Simplify™ IRT system.
  - Register existing subjects to initiate study drug shipping.
  - SKIP dispensing event #2 and/or #3 based on the subject's current study timeline
- For example:
  - CHGAF-99999-0001 was randomized on 01/01/23. Today is 04/25/23. Therefore, this subject is on Month 4 of their 12-mo study timeline.
  - Considering each study drug shipment is a 4-mo supply, register the subject for Dispensing Event #1 and SKIP Dispensing Event #2.

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.

Questions from the Group?

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/ Contact

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Thank You