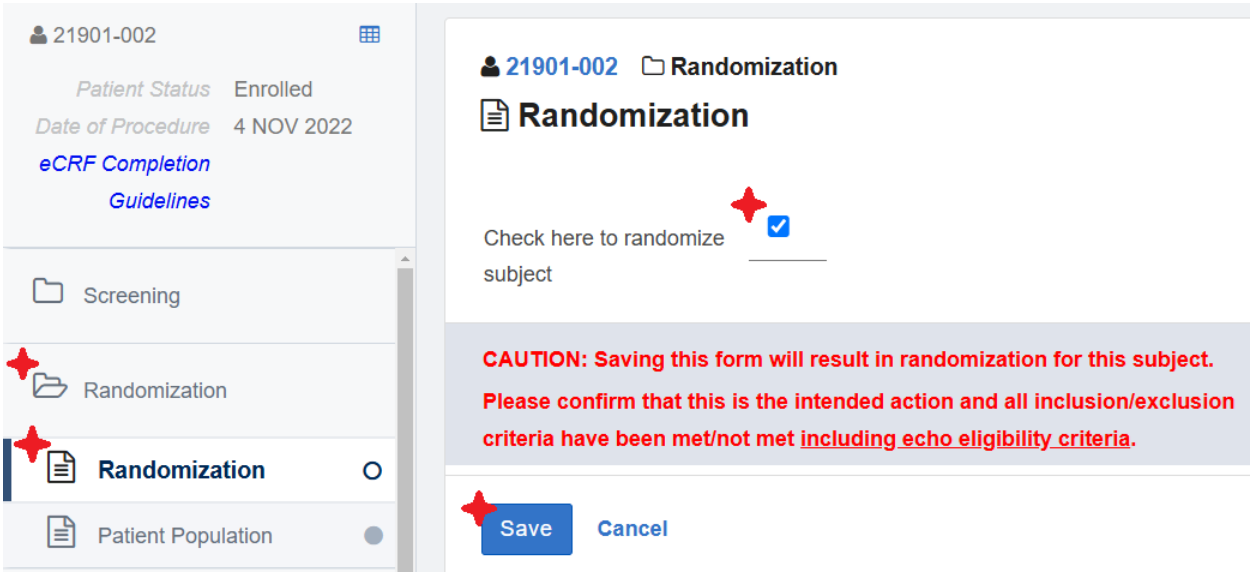
conformal™ The Shape of Stroke Prevention	**Title:** **MOP 6 - Randomization**

Randomization in EDC

- Patients in the CONFORM Study are randomized in Medidata Rave. If you do not have access to Medidata, please contact your Site Manager.
- Please read this entire form carefully before randomizing a subject. Randomization cannot be undone and must follow specific requirements per protocol.

1. **How do I randomize a subject?**
   To create a subject, select 'Add Subject' in the top right corner. Once a subject has been created in the EDC, go to the "Informed Consent" form in the Screening Visit folder. In the form, assign the patient to the 'Roll-In' or 'Randomize' cohort. If subject is to be randomized, select Randomize.

   Note: The following two pages must be completed in EDC in order to open the Randomization folder: Informed Consent and Inclusion/Exclusion Criteria. Once these two forms are complete, the Randomization folder will open. In the Randomization folder, there is a form called Randomization. Check the box in this form and save the form to randomize the patient. See screenshot below:



2. **What is required before randomization?**
   At a minimum, the following must be completed before randomization:
   - Informed Consent
   - All assessments pertaining to Inclusion/Exclusion Criteria
     - CHA2DS2-VASc
     - Medical history
     - Concomitant medications
     - Pregnancy test
     - Hematology, Chemistry - Serum Creatinine, and Coagulation
     - CT/TEE Imaging evaluating all Echocardiographic Exclusion Criteria

3. **What is the expected timeline to randomize a subject?**
   Randomization should be done no more than 14 days prior to the procedure date. The ideal time to randomize is 10-14 days prior to the scheduled procedure. This allows for the Sponsor Field Clinical Specialist team to provide case support for the CLAAS® procedure.

   Additionally, Randomization must occur no later than 90 days after informed consent is signed. Randomizations which occur more than 14 days prior to Procedure or more than 90 days after consent will require protocol deviation reports.

4. **Can I randomize a subject on the table?**
   Yes - Conformal can support same day-randomization. At the time of the procedural TEE, on-site Conformal Field Clinical Specialists will collaborate with the site PI to determine if subject has met imaging eligibility criteria. Once deemed eligible, randomization can occur via EDC.

5. **What do I do if I need to randomize a subject on the table and I can't access the EDC?**
   Call the phone number 1-866-633-4328 and select option 5 for US. The Medidata Helpdesk team will verify your credentials and can perform emergency randomization. In order to randomize, Informed Consent and Inclusion/Exclusion forms must already be completed. The Helpdesk will need the Site Number and Subject ID Number for the subject.

   You may be asked to fill out an emergency randomization form and return it to Helpdesk via fax or email.

   Please note that emergency randomization should be used in emergency situations (e.g., power outage or internet outage) and takes some time to complete.

6. **What happens if I randomized a subject by mistake?**
   If you have accidentally randomized a patient, please contact your Site Manager.