ENRGISE PILOT STUDY: ADVERSE EVENT REPORT

Date Completed ☐☐/☐☐/☐☐

Staff ID ☐☐☐☐

Rev: _____

DE: _____

Date: _____

Section 1: AE Identification *(refer to MOP Chapter 14 for detailed instructions on how to complete this form)*

1. Indicate that type of Adverse Event (***Check all that apply***)

1 ☐ Atrial Fibrillation
1 ☐ Cough
1 ☐ Dizziness/Presyncope
1 ☐ Fall (mechanical)
1 ☐ Fatigue
1 ☐ Syncope
1 ☐ GI Upset (nausea, vomiting, diarrhea, e.g.)
1 ☐ Hyperglycemia (FSBG > 300)
1 ☐ Hyperkalemia (K>5.5 mEq/L)
1 ☐ Severe Hyperglycemic Episode (HHNK or DKA)
1 ☐ Drop in hemoglobin by >20%
1 ☐ Hypotension (BP <90/50)
1 ☐ Drop in eGFR >20%
1 ☐ Acute Renal Failure
1 ☐ Angioedema
1 ☐ Stroke or TIA
1 ☐ Other, Specify → _____

2. Date of Onset: ☐☐/☐☐/☐☐

3. End Date: ☐☐/☐☐/☐☐ 1 ☐ Event Ongoing

4. Who reported this adverse event? 1 ☐ Participant 2 ☐ Proxy 3 ☐ Other → _____

5. At what visit was the AE reported?

1 ☐ SV1 2 ☐ SV2 3 ☐ BLR 4 ☐ F03 5 ☐ F06 6 ☐ F09 7 ☐ F12 8 ☐ Spontaneous 9 ☐ Safety

6. Does this AE meet the definition of Unexpected? 1 ☐ Yes 2 ☐ No

7. Please rate the severity of this AE:

1 ☐ Mild (asymptomatic or mild symptoms; clinical or diagnostic observations only; interventions not indicated)
2 ☐ Moderate (minimal, local or non-invasive intervention indicated)
2 ☐ Severe (medically significant but not immediately life-threatening; disabling; limiting self-care)

8. Was this AE related to an ancillary study? 1 ☐ Yes → 2 ☐ No

8a. Which Ancillary Study? → _____

Participant ID	☐☐☐☐☐☐☐☐	ACROSTIC	☐☐☐☐☐☐

Section 2: AE Relationship to Study

9. Was this AE related to either of the study drugs? *(**check one**)*	10. Was this AE related to any of the study procedures? *(**check one**)*
1 ☐ Not due to study drug	1 ☐ Not due to study procedure
2 ☐ Possibly due to study drug	2 ☐ Possibly due to study procedure
3 ☐ Definitely due to study drug	3 ☐ Definitely due to study procedure

Section 3: AE Action Taken

11. *Please list the actions taken, if any (**check all that apply**):*

1 ☐ No Action Taken

1 ☐ No Action Taken, Med Change Not Necessary

1 ☐ Discontinued Losartan/Placebo

1 ☐ Discontinued Fish Oil/Placebo

1 ☐ Transported participant to Acute Care Facility (e.g. ER, Hospital)

1 ☐ Contacted participant's PCP directly to discuss

1 ☐ Instructed Participant to Discuss with PCP

1 ☐ Decreased Losartan/Placebo

1 ☐ Decreased Fish Oil/Placebo

1 ☐ Counseled on storage/timing of dose for fish oil/placebo

1 ☐ Increased monitoring frequency for bloodwork

1 ☐ Increased monitoring frequency for blood pressure

1 ☐ Other → _____

Section 4: SAE Determination

12. Does this event meet the definition of serious (i.e. resulted in inpatient hospitalization, death, life-threatening condition, or major disability or disruption in ability to conduct normal life functions)?

1 ☐ Yes → **Complete SAE Report form**

2 ☐ No

Adverse Event Number ☐☐☐☐	*Record the AE# generated by the data system after saving the form.*