

# CTEP-AERS CHECK LIST

**Tab 1:** Confirm reporter & treating physician details.

**Tab 2:** Complete adverse event information (start/stop dates, verbatim term).

**Tab 3:** Describe the adverse events, including presentation, SAE treatment, clinical findings, timing, and discovery date. Document outcomes, impact of the clinical trial intervention, study removal date, and autopsy status. Be as complete as possible.

**Tab 4:** Review pre-populated information from Rave for protocol treatment arm and cycle.

**Tab 5:** List **ALL** protocol treatment(s) assigned to the patient; enter “0mg” for any study treatment not received during the SAE reporting cycle.

**Tab 6:** Enter demographics, disease information, relevant pre-existing conditions, concomitant medications that contributed to SAE, and relevant prior therapies.

**Tab 7:** Note any other contributing circumstances, if applicable.

**Tab 8:** Enter relevant lab results.

**Tab 9:** Assign attributions to protocol treatment, disease, and other causes; at least one positive attribution is required for each event.

**Tab 10:** Confirm data accuracy, including physician sign-off and supporting documents. Confirm submitter and recipient details, then submit the report. A successful submission will provide a green checkmark.