**Definitions for Enrollment Numbers**

**Screened Participants:** individuals who have given informed consent and participated in screening procedures to determine eligibility. Note that informed consent is required before any screening procedures are conducted.

**Screen failures:** Participant(s) removed from the study during the screening process because they did not meet all inclusion and exclusion criteria, or other requirements that must be met for research participation. Participant(s) who leave the study after randomization or assignment to study treatment should be counted as withdrawals rather than screen failures, even if the participant did not start the study treatment.

**Enrolled Participants:** individuals who are eligible for participation (i.e., meet the inclusion criteria for the study), have given informed consent (if applicable), completed the procedures that determine eligibility (if applicable) and participated in some or all study procedures.

**Withdrawal:** Participant(s) are considered to have been withdrawn/discontinued from the research when the participant(s) either stopped participation or the research team stopped the participant's participation early for reasons other than reaching a study endpoint. Do not count screen failures when reporting withdrawals.

**Participant Deaths:**

* Because some protocols anticipate that a participant may pass away during the research / during long term follow up, and include death as a possible endpoint, a participant who passes away may be counted among the completed participants on the report.
* If the protocol does not have death as a study endpoint, a participant who passes away would be considered a withdrawal (enter in the field for “How many subjects decided on their own to stop taking part in the research?”)