COSMOS
Navigate the Compliance Universe

42 C.F.R. § 11.48

What constitutes clinical trial results information?

(a) For each applicable clinical trial, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, for which clinical trial results information must be submitted under § 11.42, the responsible party must provide the following:

(1) *Participant flow.* Information for completing a table documenting the progress of human subjects through a clinical trial, by arm, including the number who started and completed the clinical trial. This information must include the following elements:

(i) *Participant Flow Arm Information.* A brief description of each arm used for describing the flow of human subjects through the clinical trial, including a descriptive title used to identify each arm;

(ii) *Pre-assignment Information.* A description of significant events in the clinical trial that occur after enrollment and prior to assignment of human subjects to an arm, if any; and

(iii) *Participant Data.* The number of human subjects that started and completed the clinical trial, by arm. If assignment is based on a unit other than participants, also include a description of the unit of assignment and the number of units that started and completed the clinical trial, by arm.

(2) *Demographic and baseline characteristics.* Information for completing a table of demographic and baseline measures and data collected by arm or comparison group and for the entire population of human subjects who participated in the clinical trial. This information must include the following elements:

(i) *Baseline Characteristics Arm/Group Information.* A brief description of each arm or comparison group used for describing the demographic and baseline characteristics of the human subjects in the clinical trial, including a descriptive title used to identify each arm or comparison group.

(ii) *Baseline Analysis Population Information*—(A) *Overall Number of Baseline Participants.* The total number of human subjects for whom baseline characteristics were measured, by arm or comparison group and overall.

(B) *Overall Number of Units Analyzed.* If the analysis is based on a unit other than participants, a description of the unit of analysis and the number of units for which baseline measures were measured and analyzed, by arm or comparison group and overall.

(C) *Analysis Population Description.* If the Overall Number of Baseline Participants (or units) differs from the number of human subjects (or units) assigned to the arm or comparison group and overall, a brief description of the reason(s) for the difference.

(iii) *Baseline Measure Information.* A description of each baseline or demographic characteristic measured in the clinical trial, including age, sex/gender, race, ethnicity (if collected under the protocol), and any other measure(s) that were assessed at baseline and are used in the analysis of the primary outcome measure(s) in

accordance with § 11.48(a)(3). The description of each measure must include the following elements:

(A) Name and description of the measure, including any categories that are used to submit Baseline Measure Data.

(B) *Measure Type and Measure of Dispersion:* For each baseline measure submitted, an indication of the type of data to be submitted and the associated measure of dispersion.