

**FDA-AE-T09**  
**Subjects With Serious Adverse Events by System Organ Class and Preferred Term**  
**Safety Population**

<b>System Organ Class Preferred Term [1]</b>	<b>Xanomeline Low Dose (N=XX) n (%)</b>	<b>Xanomeline High Dose (N=XX) n (%)</b>	<b>Placebo (N=XX) n (%)</b>	<b>Risk Difference (%) (95% CI) [2]</b>	<b>Risk Difference (%) (95% CI) [3]</b>
Subjects with at least one treatment-emergent SAE [4]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
SOC {alphabetical order}	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
PT {alphabetical order}	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)

Source: ADAE; Program name: fda-ae-t09.sas;

Abbreviations: CI, confidence interval; MedDRA, Medical Dictionary for Regulatory Activities; N, number of subjects in treatment arm; n, number of subjects with at least one event; SOC, System Organ Class; PT, Preferred Term.

Note: Subjects are counted once within each system organ class and preferred term.

[1] All adverse events were coded using MedDRA version xx.x.

[2] Difference is shown between Xanomeline Low Dose vs. Placebo.

[3] Difference is shown between Xanomeline High Dose vs. Placebo.

[4] Treatment-emergent adverse event is defined as AE with onset after the first dose of study drug. SAE is defined as any untoward medical occurrence that, at any dose that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent incapacity or substantial disruption of the ability to conduct normal life functions, or is a congenital anomaly or birth defect.