

Time of occurrence of first SAEs	Month-3	Month-6	Month-12	Month-24
Probability of SAEs occurrence (95% CI)	16.9 (13.1-21.9)	24.2 (19.5-29.7)	29.7 (24.6-35.6)	33.9 (28.4-40.2)
No. of patients at risk	228	209	161	108

Time of occurrence of death or SAEs	Month-3	Month-6	Month-12	Month-24
Probability of SAEs occurrence (95% CI)	17.3 (13.4-22.2)	24.4 (19.8-29.9)	31.3 (26.1-37.8)	37.8 (31.1-43.2)
No. of patients at risk	226	197	160	99

SAEs: severe adverse events CI: confidence interval