## 1. Distribution of Days on Study to AE Onset for Subjects with AE



## 2. Cumulative incidence

Protocol: XYZ12345 Study 099
Population: Intent-to-Treat
Cumulative Incidence (SE) of Gastrointestinal Adverse Events of Concern by Time of Initial Onset


Subjects At Risk

| Drug A | 216 | 200 | 190 | 187 | 181 | 173 | 172 | 164 |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| Drug B | 431 | 363 | 334 | 319 | 304 | 296 | 291 | 284 |

Note: Gastrointestinal AE of Concern are: Nausea, Abdominal Pain, Diarrhea, and Vomiting USER ID:/aedia04.sas 02NOVO4 10:51

## 3. Hazard Ratio and 95\% CI of Time Progression


4. Time trends in incidence of AEs (diagonal) and chance-corrected joint incidence (off-diagonal).


## 5. AE with time of observation data


6. Variable Clustering of AEs at Week 1, Using Proportion of Patients Had AEs as Similarity


