# Event prediction in event-driven trials

## Description

The simulation report presents a summary of event predictions for Phase II or Phase III trials with an event-driven design. Blinded event data at an interim analysis are used to forecast the number of events at pre-defined time points in the future.

## Table 1. Trial parameters

| **Parameter**  | **Value** |
| --- | --- |
| Timing of the interim analysis | 12 |
| Future time points for computing event predictions | 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24 |

## Table 2. Prior distribution parameters

| **Parameter**  | **Value** |
| --- | --- |
| Event hazard rate | Alpha = 11.11, Beta = 240.45 |
| Patient dropout hazard rate | Alpha = 11.11, Beta = 1282.4 |
| Patient enrollment rate | Alpha = 11.11, Beta = 0.32 |

Shape (alpha) and rate (beta) parameters of the prior gamma distributions for the event and patient dropout hazard rates as well as the intensity rate of the patient enrollment process.

## Table 3. Simulation parameters

| **Parameter**  | **Value** |
| --- | --- |
| Number of simulations | 1000 |

## Table 4. Event prediction at pre-defined time points

| **Time point** | **Mean number of events** | **95% predictive interval** |
| --- | --- | --- |
| 12 | 105 | (105, 105) |
| 13 | 121.6 | (114, 131) |
| 14 | 138.9 | (127, 152) |
| 15 | 157.5 | (143, 173) |
| 16 | 176 | (157, 196.02) |
| 17 | 195.8 | (175, 219.02) |
| 18 | 216.5 | (191, 242) |
| 19 | 237.5 | (211, 265) |
| 20 | 259.4 | (229, 292) |
| 21 | 281.4 | (247, 317) |
| 22 | 304 | (265, 345.02) |
| 23 | 328.1 | (286, 372) |
| 24 | 353.3 | (308, 403) |

Number of events at the interim analysis: 105.

## Figure 1. Event prediction at pre-defined time points



Black curve: Observed events. Red curve: Predicted mean number of events. Gray band: 95% predictive interval.