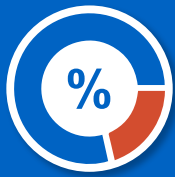


Cumulative Incidence and Exposure-Adjusted Incidence Rate

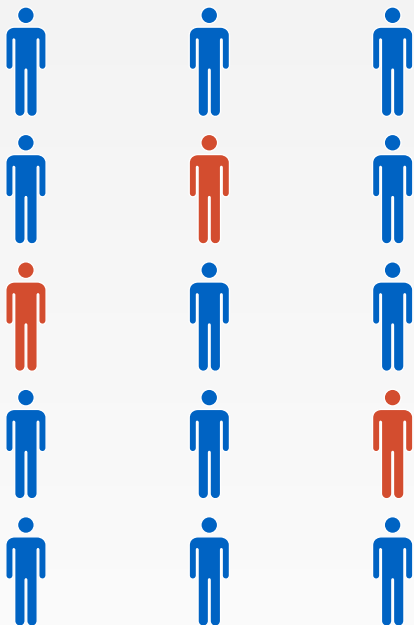
Cumulative Incidence



Proportion of patients experiencing the event

- Does not consider the timing of the event
- Includes cumulative incidence over the observation or follow-up period
- Reported as percentage of patients with the event
- Routinely used metric in safety analyses for studies with similar follow-up period between treatment groups

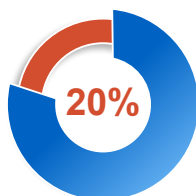
$$\text{Cumulative incidence} = \frac{\text{Number of patients with the event (n)}}{\text{Total number of patients at risk (N)}} \times 100\%$$



n = 3 patients; N = 15 patients

$$\text{Cumulative incidence} = \frac{3}{15} \times 100\% = 20\%$$

In this example, a cumulative incidence of 20% is observed for the event of interest



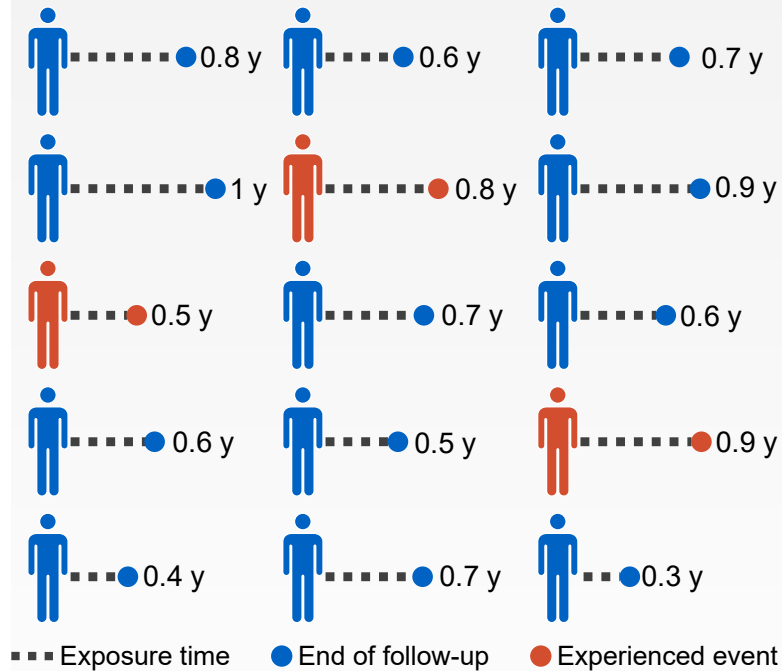
Exposure-Adjusted Incidence Rate



Number of patients who experienced the event per total patient-years of follow-up

- Accounts for the timing of the first event during the follow-up, assuming constant risk over time
- Exposure time adjustment includes the time until initial occurrence of an event or end of follow-up for those without an event
- Standardized measure of risk per 100 patient-years
- Commonly used to summarize safety data in long-term studies with potential differences in the follow-up duration between treatment groups

$$\text{Exposure-adjusted incidence rate (r)} = \frac{\text{Number of patients with the event (n)}}{\text{Total exposure time for all patients at risk (t)}} \times 100$$



n = 3 patients; t = 10 patient-years

$$r = \frac{3}{10} \times 100 = 30 \text{ patients per 100 patient-years}$$

In this example, an exposure-adjusted incidence rate estimates that if 100 patients were treated for 1 year, 30 patients would experience the event of interest