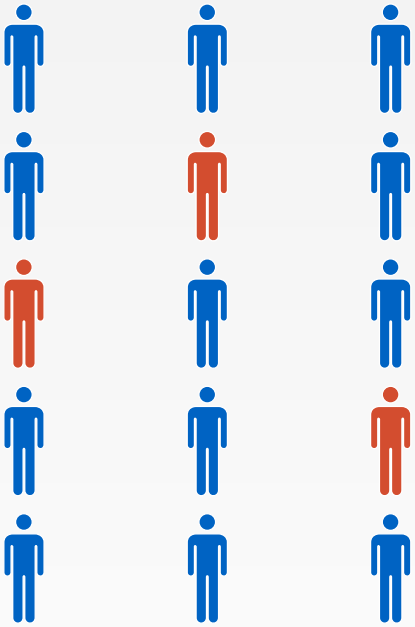
Cumulative Incidence and Exposure-Adjusted Incidence Rate

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**

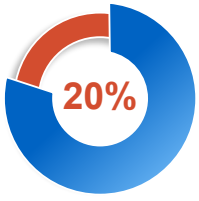
$$\text{Cumulative incidence} = \frac{\text{Number of patients with the event (n)}}{\text{Total number of patients at risk (N)}} \times 100\%$$



n = 3 patients; N = 15 patients

Cumulative incidence = $\frac{3}{15}$ x 100% = **20%**

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

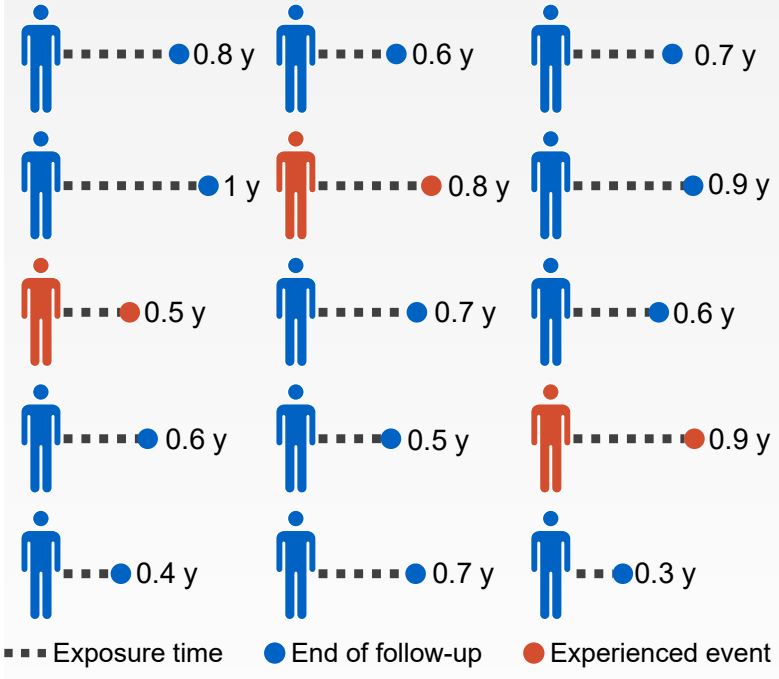


Exposure-Adjusted Incidence Rate

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 = $\frac{3}{10}$ x 100 = **30 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

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