

PP09 Final Results from a TEAE Scenario Survey by the PHUSE Treatment Emergence Definition Project Team

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Background

The PHUSE Best Practices for Data Collection Initiatives project team conducted a survey in 2020 to study the variation in the collection and definition of treatment emergent adverse events (TEAEs) in clinical studies and noted the need to pursue additional research to further harmonize industry practices.

The PHUSE Treatment Emergence Definition project team conducted an additional survey to solicit input from respondents on various TEAE scenarios for a basic study design and the final results are reported in this poster. Respondents (N = 273) were asked to review each scenario and indicate whether they thought the patient had a TEAE for an intervention period summary table.

Assumptions

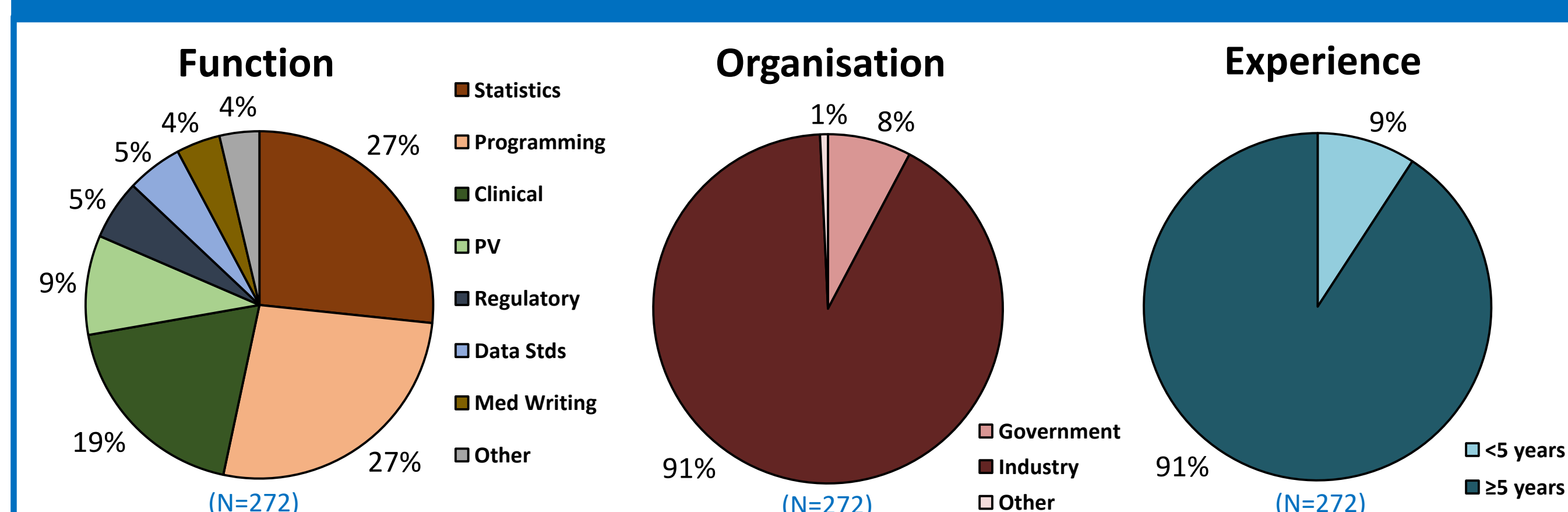
Two-period, two-treatment design:

- Screening period = patients undergo typical screening assessments and receive no treatment
- Intervention period = patients receive active drug or control throughout entire period and there are no dosing modifications
- There is no safety follow-up period

Adverse event scenarios:

- Each scenario represents the reported AE(s) for a single patient
- Event onset, recurrence, and severity can vary over time, however, changes in drug relatedness or seriousness are out of scope
- Each event is the same medical concept for the patient and everything is known about the events

Respondent Characteristics



Conclusions

A basic study design was utilized with not uncommon scenarios, yet considerable disagreement in responses was noted:

- How to define TE in the presence of screening period events
- How to define TE when the event severity decreased after the start of treatment
- How to define TE when there is a gap in time between the screening period event and its re-emergence after the start of treatment

No meaningful differences were noted in responses when accounting for respondent characteristics (i.e., function, organisation, or experience) (*not shown*).

These results indicate that there is a definite need for more consistency in how to define and interpret TE in clinical trials.

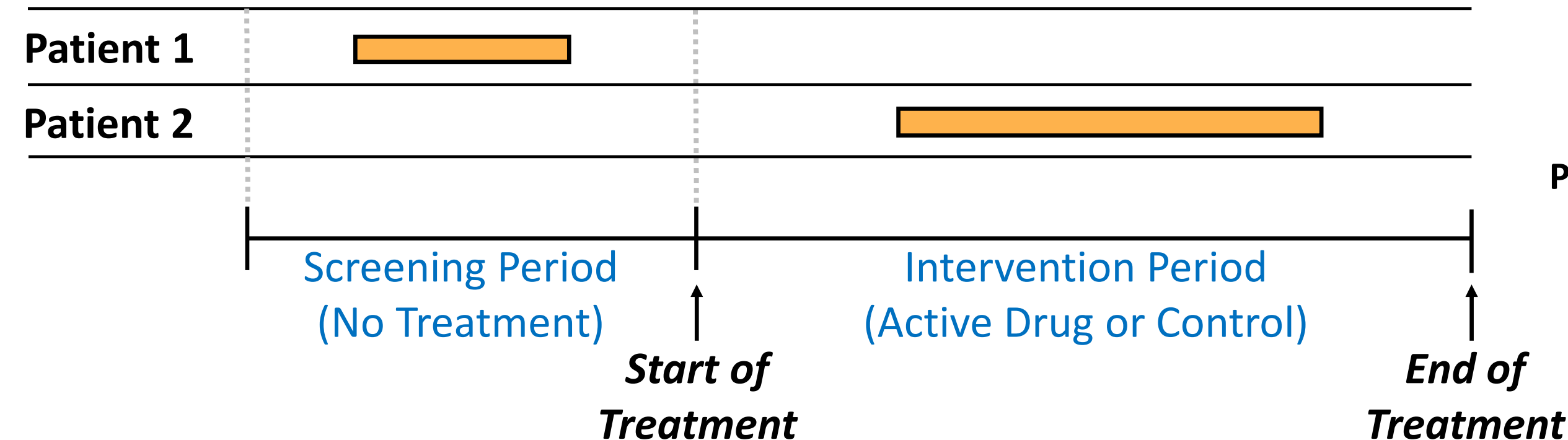
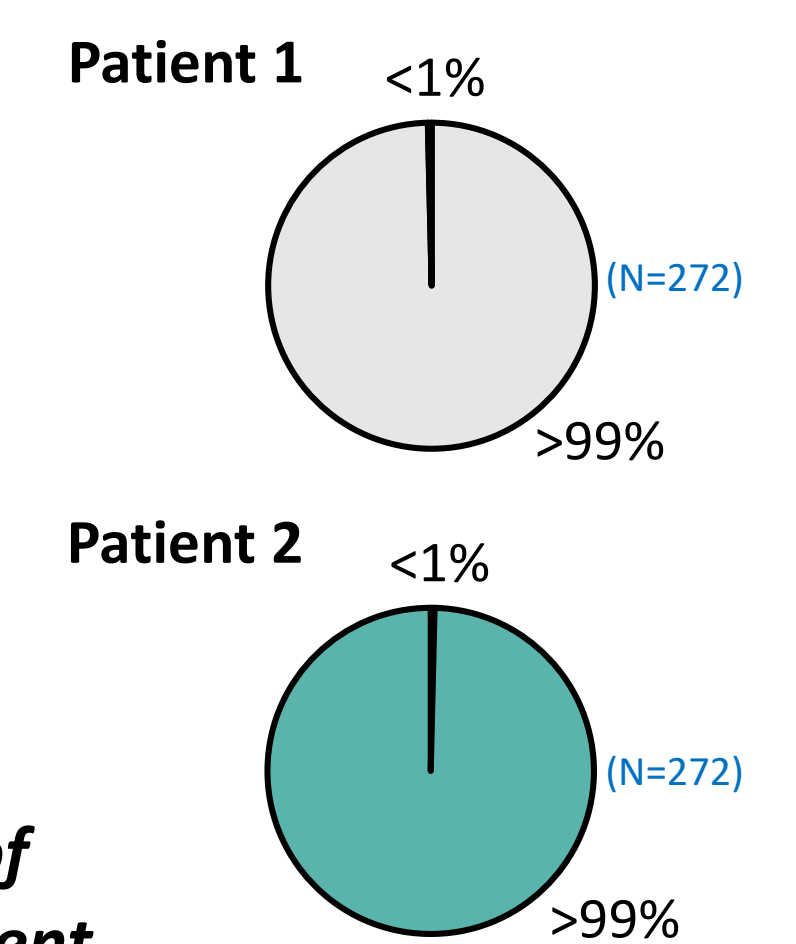
TE Scenarios and Final Survey Results

Event Severity

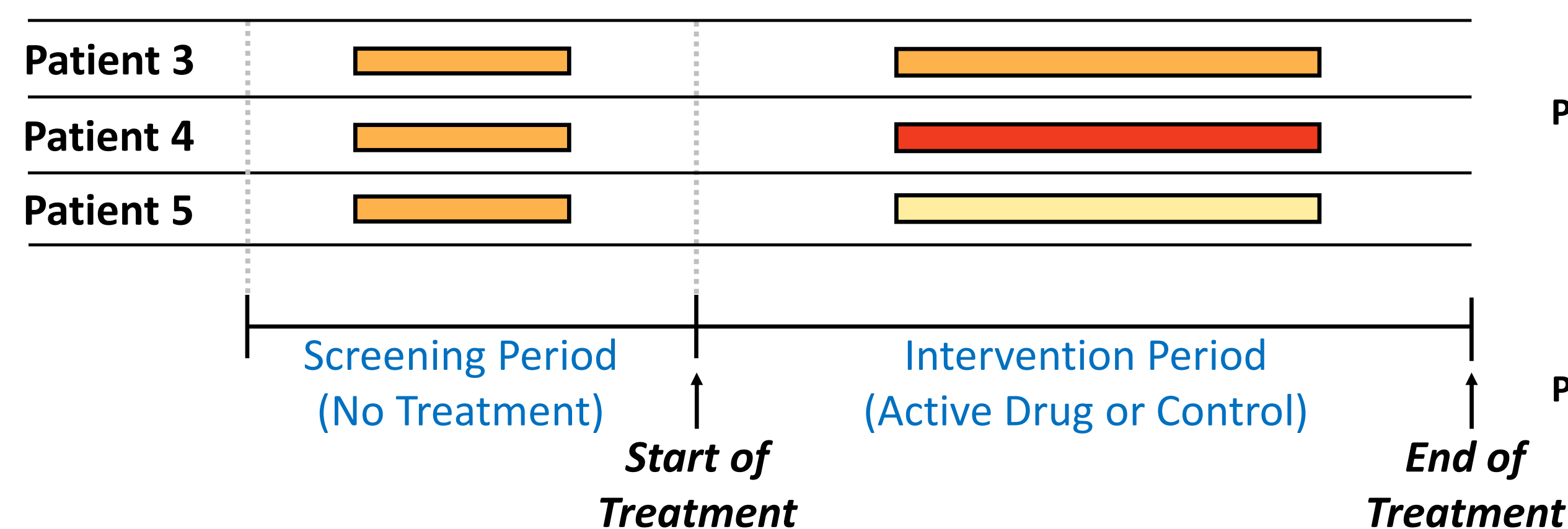
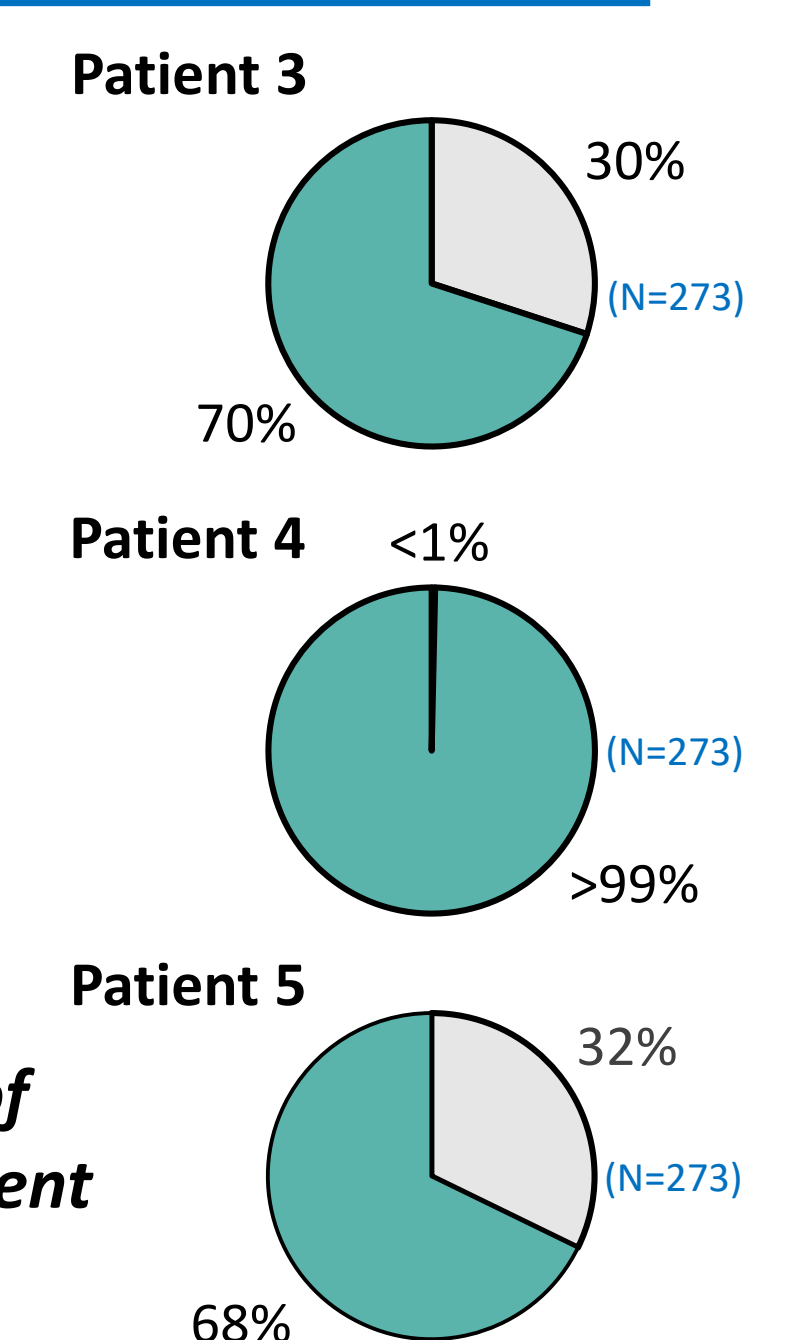
Mild Moderate Severe

No Yes

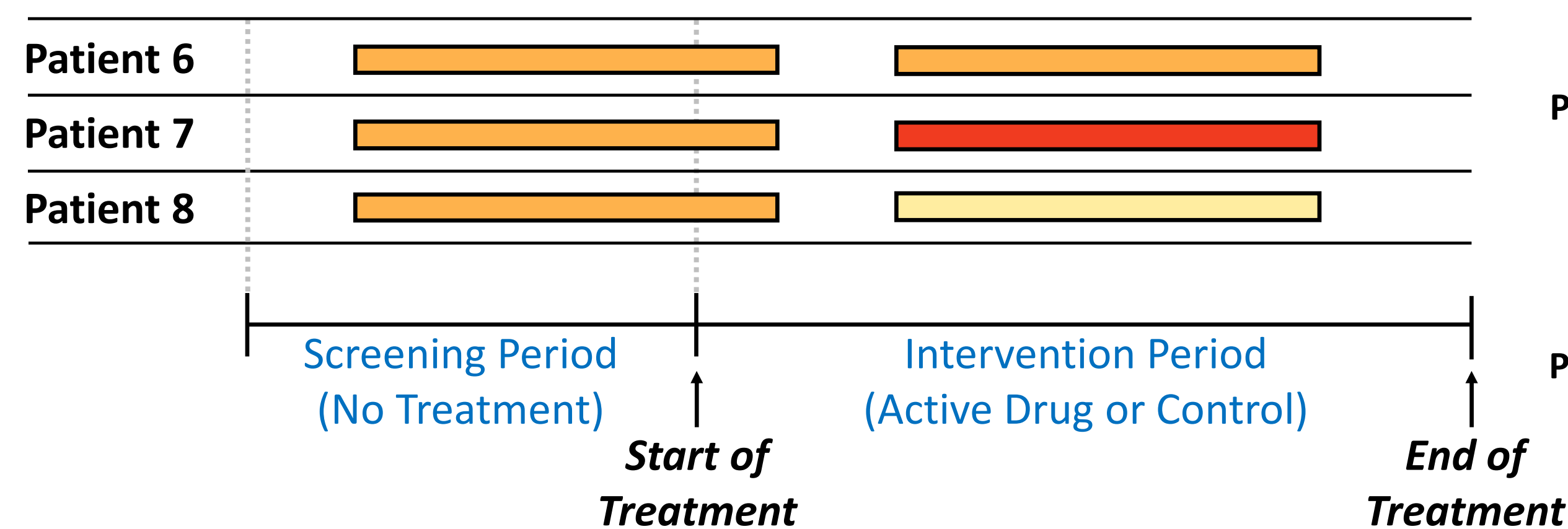
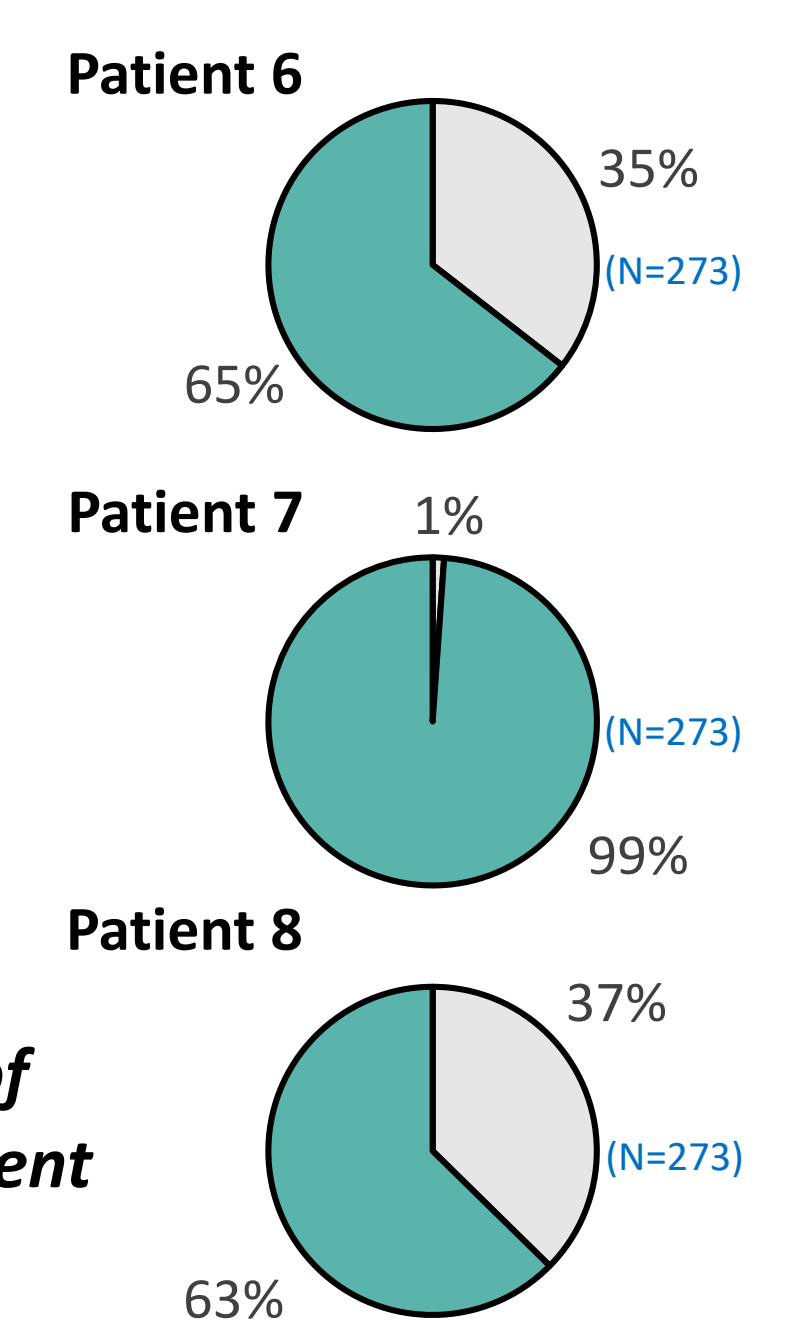
Event starts/ends within same period



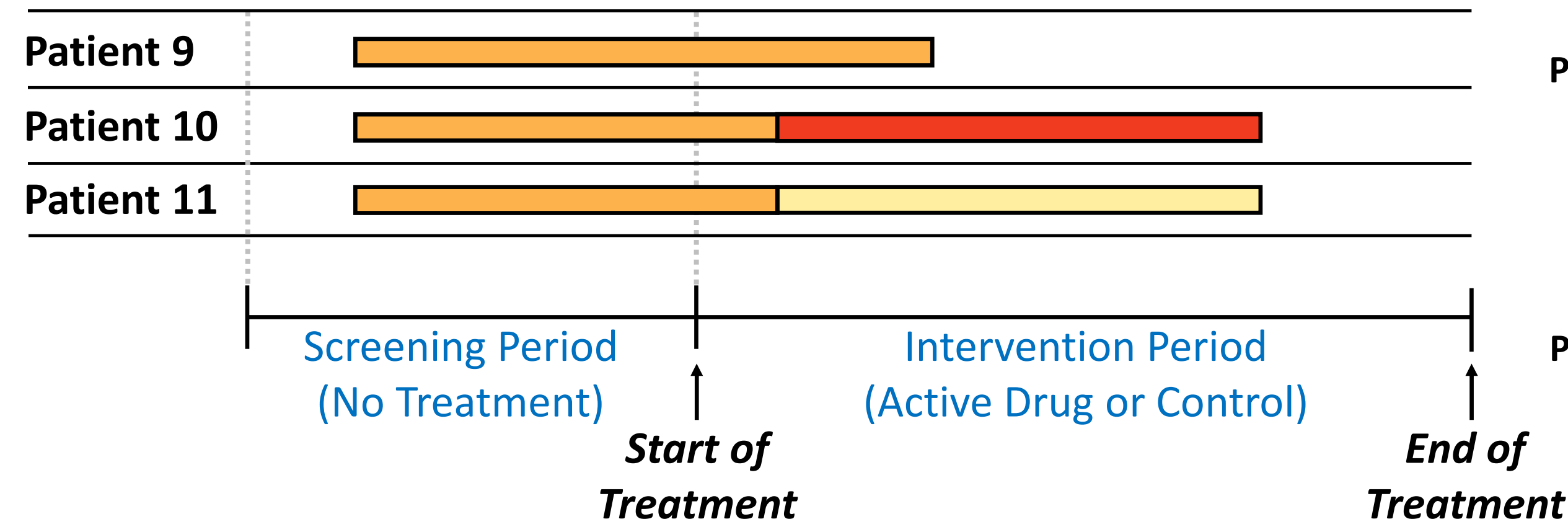
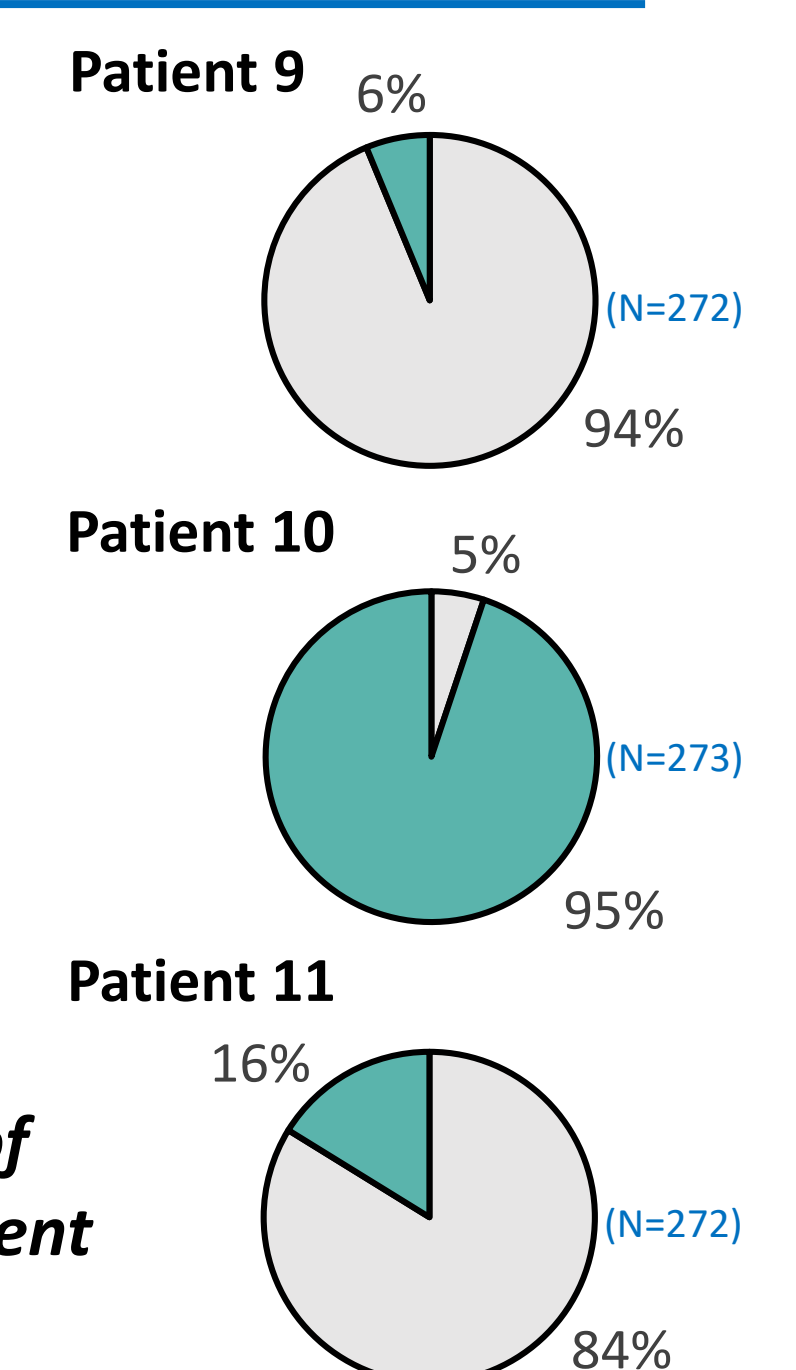
Event starts/ends during Screening Period and returns during Intervention Period



Event starts during Screening Period, ends during Intervention Period, and returns again



Event starts during Screening Period and ends during Intervention Period



Event starts during Screening Period, changes severity more than once, and ends during Intervention Period

