

Quantifying the Effect of Treatment Switch:

an illustration with the prevalent new user design

BACKGROUND

In real-world evidence (RWE) studies, patients often switch from one treatment to another, complicating the use of traditional new user design that restricts the analysis to treatment-naïve patients to estimate treatment effects. There is a lack of comprehensive tutorials on how to implement the prevalent new user design, which accounts for treatment history and confounding factors among all prevalent treatment users.

OBJECTIVES

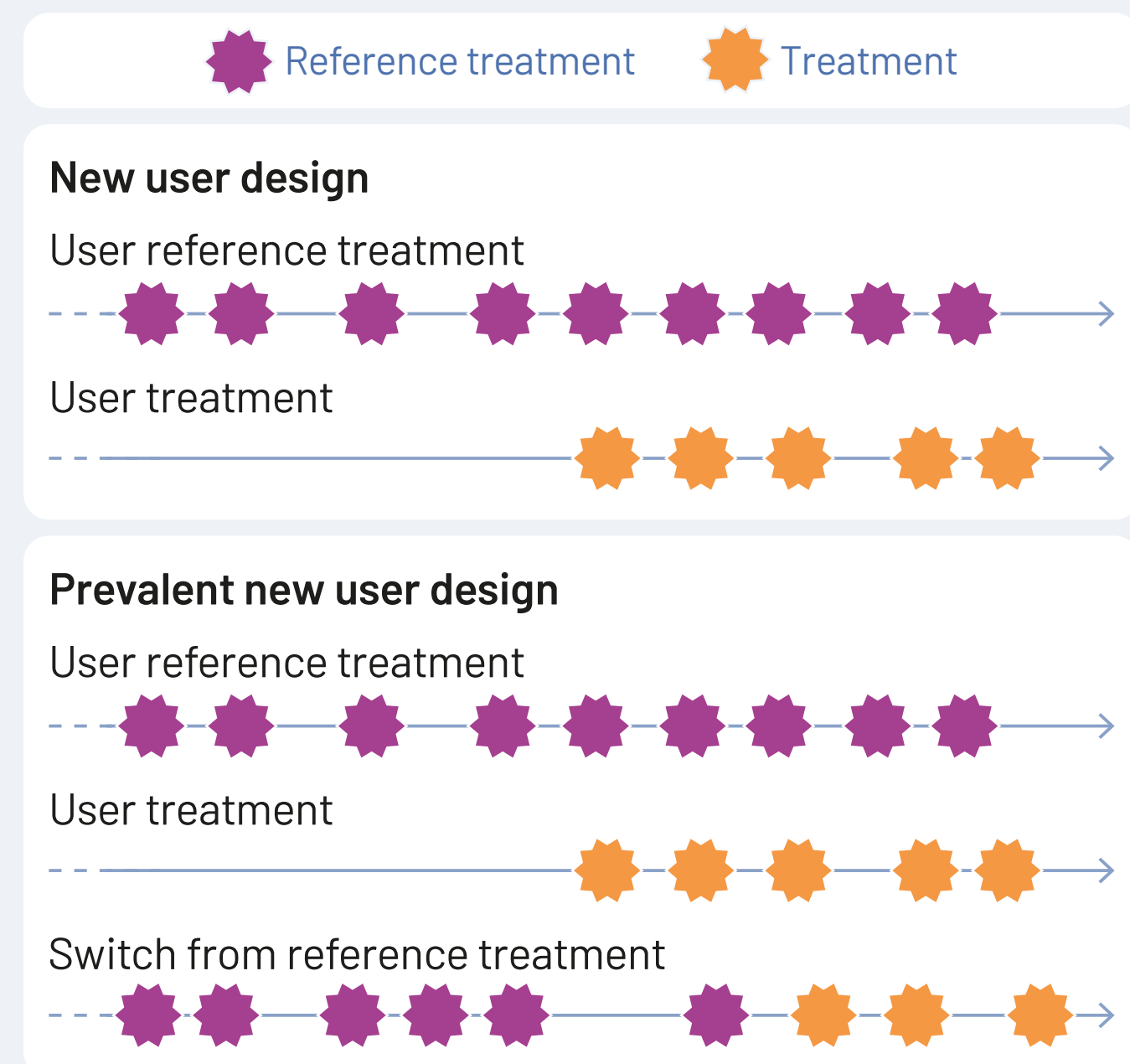
To provide a step-by-step guide for implementing the prevalent new user design, with an illustration and programming example using real-world evidence data.

METHOD

Generalities

The new user (NU) design allows the comparison of new user of both treatment. The prevalent new user (PNU) design allows the comparison of new user of both treatment AND switchers between treatments¹.

The illustration demonstrates these steps using French National Health Data System (SNDS) dataset of patients treated for respiratory diseases. The effect of treatment switches on mortality was taken as the main outcome of interest.



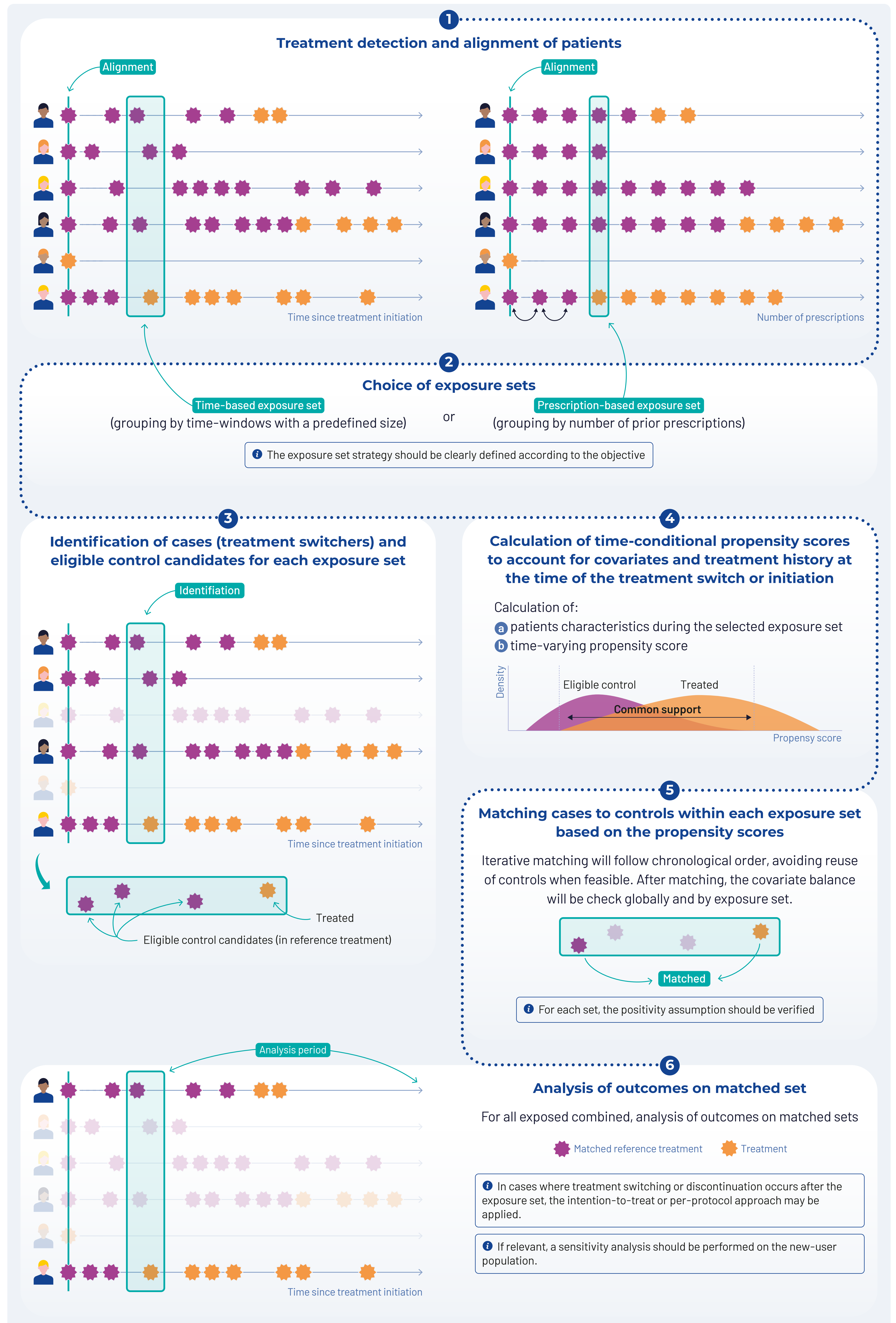
Comparison of PNU and NU design

PNU design	NU design
Population representativeness/sample size	
✔ Include real-world users (e.g., switchers); better external validity	✘ Often exclude chronic users; may lack generalizability
Bias Control	
⚠ Needs explicit alignment of index date and time-varying exposure sets	✔ Easier to control since follow-up starts at first exposure
Design Complexity	
✘ More complex (requires exposure set definition, time-conditional PS, iterative matching, decision on re-use control or not)	✔ Simpler design and analysis steps

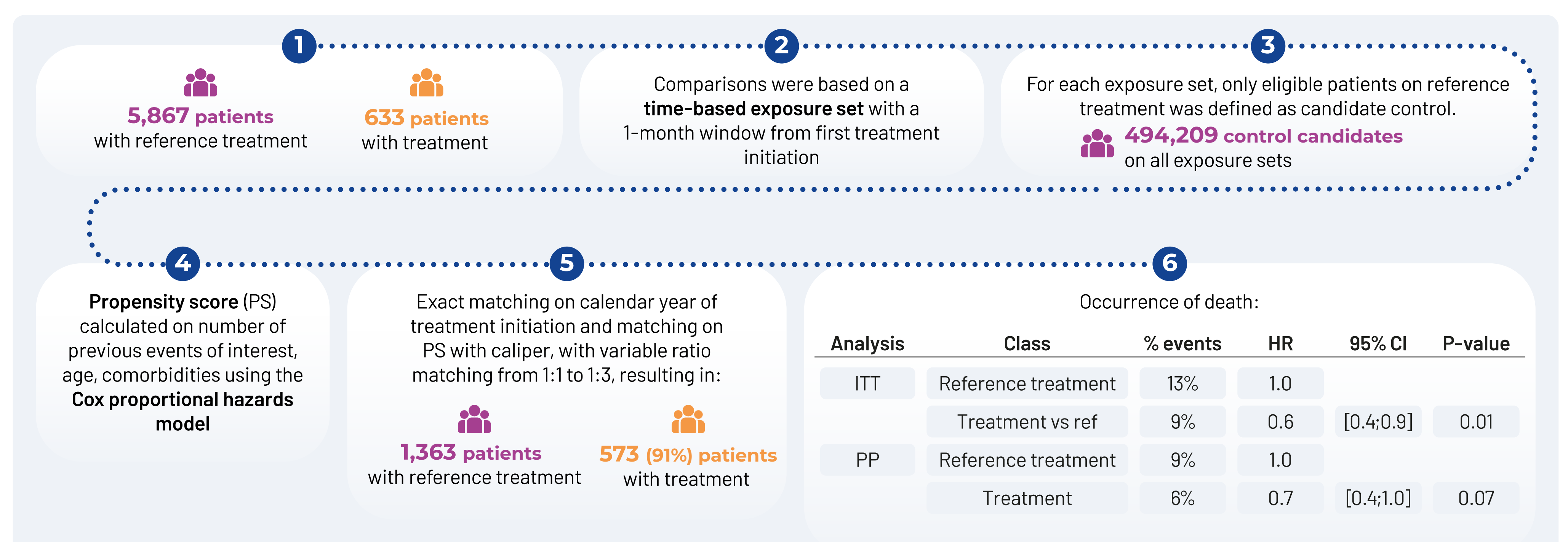
CONCLUSION

The prevalent new user design offers a powerful approach for evaluating treatment switches in RWE studies. This step-by-step guide demonstrates its potential and feasibility using standard programming software.

PREVALENT NEW USER DESIGN: STEP-BY-STEP PIPELINE



RESULTS



¹ Suissa S, Moodie EE, Dell'Aniello S. Prevalent new-user cohort designs for comparative drug effect studies by time-conditional propensity scores. *Pharmacoepidemiol Drug Saf.* 2017 Apr;26(4):459-468. doi: 10.1002/pds.4107. Epub 2016 Sep 9. PMID: 27610604.