Recruitment rate stochasticity at the design stage of a clinical trial

Supervision by Malgorzata Roos

Pilar Pastor

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Why recruitment rates?

- – Timely recruitment vital to the success of a clinical trial
- – Inadequate number of subjects $\rightarrow$ lack of power
- – Recruitment period too long $\rightarrow$ competing treatments
- – Recruitment of patients varies at each stage
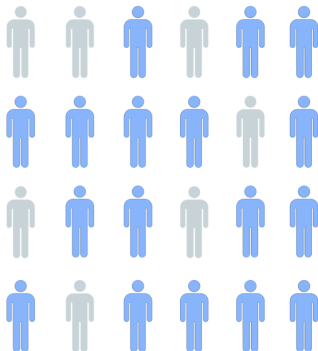- – Accrual = Cumulative Recruitment
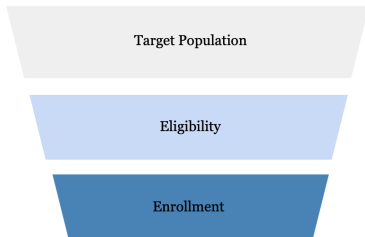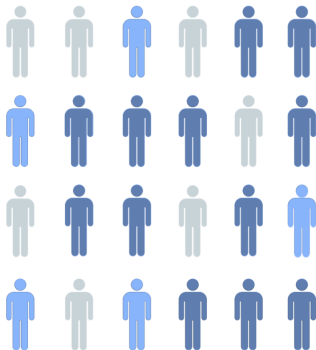- – Carter (2004)
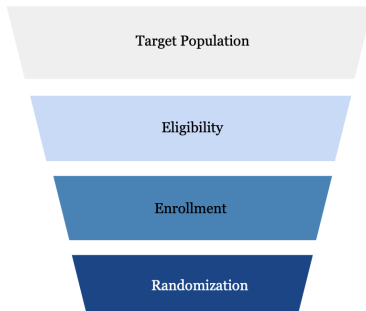
Target Population

Target Population
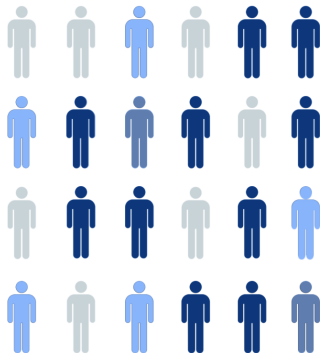
Eligibility

Target Population
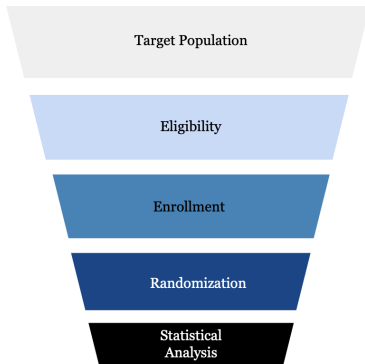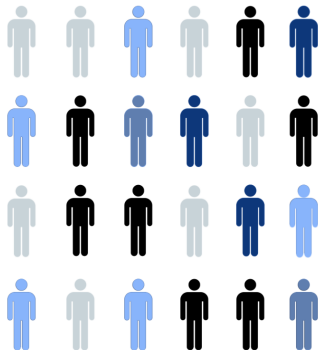
Eligibility

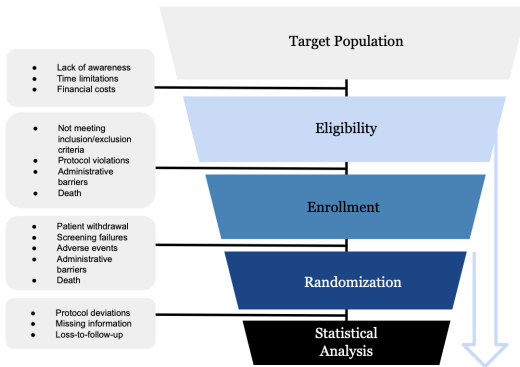# Enrollment

Randomization

Statistical Analysis

Patient Attrition

Uncertainty

– **Aleatory**: randomness inherent and unpredictable
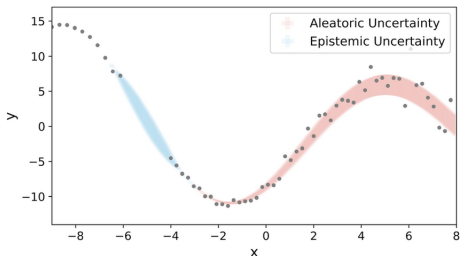– **Epistemic**: arises from limited knowledge about parameters

Figure: Visualization of two types of uncertainty (Yang and Li, 2023)

Models for Counts

Methods	Counts	Expectation	Variance	Aleatory	Epistemic
Expectation	$C(t) = \lambda t$	λt	0	No	No
Poisson	$C(t) \sim \mathrm{Po}(\lambda t)$	λt	λt	Yes	No
Negative Binomial	$C(t) \sim \mathrm{Po}(^-t); \Lambda \sim \mathrm{G}(\alpha, \beta)$	$\frac{\alpha}{\beta}$	$\frac{\alpha(\beta+1)}{\beta^2}$	Yes	Yes

Table: Aleatory and epistemic uncertainty in accrual shown by
different models for counts.

Shrunk Slide 1

Shrunk slide 2

Results

Conclusion

Next steps

References

Carter, R. E. (2004). Application of stochastic processes to
participant recruitment in clinical trials. *Controlled clinical trials*,
25(5):429–436.

Yang, C.-I. and Li, Y.-P. (2023). Explainable uncertainty
quantifications for deep learning-based molecular property
prediction. *Journal of Cheminformatics*, 15(1):13.