

□□□□ Over-fitting□	□□□□□□□□□□ □□□□□□□□□□□□□□□□□□□□□□□□ □□□□□□□□□□
□□□□ Interaction□	□□□□□□□□□□□□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□

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□□□□	Over-fitting
□□□□	Interaction
□□□□	Stratified randomization
□□□	Covariate
□□□□	Sampling error
□□	Bias
□□□□	Sensitivity analysis

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[1] Altman D, Dore C. Randomization and baseline comparisons in clinical trials. *The Lancet*, 1990, 335(8682):149-53.

[2] Beach M L, Meier P. Choosing covariates in the analysis of clinical trials. *Controlled Clinical Trials*, 1989, 10(4):161-175.

[3] Committee for Proprietary Medicinal Products (CPMP), Points to consider on adjustment for baseline covariates. *Statistics in Medicine*, 2004, 23:701-709.

[4] D. Tu, K. Shalay, and J. Pater. Adjustment of treatment effect for covariates in clinical trials: statistical and regulatory issues. *Drug Information Journal*, 2000, 34:511-523.

[5] EMA. Guideline on adjustment for baseline covariates in clinical trials. 2015.

[6] FDA. Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics with Continuous Outcomes. Guidance for Industry (DRAFT GUIDANCE). 2019.

[7] G. Raab, S. Day, and J. Sales, How to select covariates to include in the analysis of a clinical trial. *Controlled Clinical Trials*, 2000, 21:330-342.

[8] S. Assmann, S. Pocock, L. Enos, and L. Kasten, Subgroup analysis and other (mis)uses of baseline data in clinical trials. *The Lancet*, 2000, 255:1064-1069.

[9] Senn S. Covariate imbalance and random allocation in clinical trials. *Statistics in Medicine*, 1989, 8(4):67–75.

[10] Tukey J W. Use of Many Covariates in Clinical Trials. *International Statistical Review*, 1991, 59(2):123-137.

[11] [REDACTED] . [REDACTED] . [REDACTED] . [REDACTED] . 2018. 202-210.

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