

RADIOLOGICAL SOCIETY OF NORTH AMERICA
CLINICAL TRIALS METHODOLOGY WORKSHOP
January 2023

RECOMMENDED READING IN ADVANCE OF THE WORKSHOP

Students are urged to familiarize themselves with this material in advance of the workshop.

Faculty from this workshop have recently published the following book that provides an excellent foundation of the material that will be covered at the workshop.

[Handbook for Clinical Trials of Imaging and Image-Guided Interventions](#) ISBN: 9781118849750 (hard copy and on-line version available)

Biostatistics Concepts

1. Review concepts in biostatistics including:
 - a. Summarizing data using descriptive and exploratory analyses.
 - b. Measures of central tendency and variation.
 - c. Translating clinical research questions to statistical (testable) hypotheses.
 - d. Understanding two types of errors in hypothesis testing (type I and type II).
 - e. Interpreting p -values and confidence intervals.
 - f. Differences between correlation vs. agreement vs. accuracy.
 - g. Basic idea of regression and survival analysis.
2. Any biostatistics textbook will cover these concepts. For example, Dawson B, Trapp RG. Basic & Clinical Biostatistics. 4th ed. Lange Medical Books-McGraw-Hill, 2004: Chapters 4-6 present basic material you need to know. It will also be useful to have some familiarity with concepts from correlation and regression analysis (Ch 8) and survival analysis (Ch 9).
3. The series of articles: Fundamentals of Clinical Research for Radiologists AJR 2001-2006. The complete series can be found on the CTMW workshop website (https://www2.rsna.org/re/CTMW2023/index_files/Fundamentals_of_Clin_Res_for_Radiologists.pdf).
4. The "Statistical Concepts Series" published in Radiology in 2003-2004. The complete series can be found on the CTMW workshop website (https://www2.rsna.org/re/CTMW2023/index_files/Radiology%20Statistical%20Concepts%20Series.pdf).

Other Concepts

1. Jarvik JG. The research framework. [AJR 2001; 176: 873-78.](#)
2. Gazelle GS, Kessler L, Lee DW, McGinn T, Menzin J, Neumann PJ, van Amerongen D, White LA. A Framework for Assessing the Value of Diagnostic Imaging in the Era of Comparative Effectiveness Research. [Radiology, 2011; 261: 692-698](#)
3. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? [JAMA 2000; 283\(20\): 2701-11.](#)

And if applicable to your area of research:

4. Bossuyt P, Reitsma J, Bruns D, Gatsonis C, Glasziou P, Irwig L, Lijmer J, Moher D, Rennie D, de Vet HC. Standards for Reporting of Diagnostic Accuracy steering group. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. [Radiology 2003;226:24-28.](#)
5. Herman CR, Gill HK, Eng J, Fajardo LL. Screening for preclinical disease: test and disease characteristics. [AJR 2002; 179: 825-31.](#)
6. Mankoff, DA, Pryma DA, Clark AS. Molecular Imaging Biomarkers for Oncology Clinical Trials. [J Nucl Med 2014 55:525-528.](#)
7. Clinical Trials with Biologic Primary Endpoints in Immuno-oncology: Concepts and Usage. <https://doi.org/10.1158/1078-0432.CCR-21-1593>
8. A Data Infrastructure for Clinical Trial Diversity. David Blumenthal, M.D., M.P.P., and Cara V. James, Ph.D. https://www.nejm.org/doi/full/10.1056/NEJMp2201433#article_references
9. Pitfall in the Design and Analysis of Comparative Oncology Trials With a Time-to-Event Endpoint and Recommendations. Zachary R. McCaw, PhD ,1 Dae Hyun Kim, MD, ScD,2 Lee-Jen Wei, PhD 3. <https://doi.org/10.1093/jncics/pkac007>
10. A phase I/II seamless dose escalation/expansion with adaptive randomization scheme (SEARS). <https://journals.sagepub.com/doi/abs/10.1177/1740774513500081>
11. Design of Phase III Clinical Trials. Stephen L. George https://www2.csc.unc.edu/impact7/sites/default/files/OncologyClinicalTrials_Design_of_phase_III_clinical_trials.pdf
12. An Overview of Phase 2 Clinical Trial Designs. Pedro A. Torres-Saavedra, PhD, and Kathryn A. Winter, MS. [https://www.redjournal.org/article/S0360-3016\(21\)02611-0/fulltext](https://www.redjournal.org/article/S0360-3016(21)02611-0/fulltext)
13. Designing Phase 0 Cancer Clinical Trials. <https://aacrjournals.org/clincancerres/article/14/12/3675/72663/Designing-Phase-0-Cancer-Clinical-Trials>
14. Adaptive Designs for Clinical Trials. <https://www.nejm.org/doi/full/10.1056/nejmra1510061>
15. Analysing data from patient-reported outcome and quality of life endpoints for cancer clinical trials: a start in setting international standards. [http://dx.doi.org/10.1016/S1470-2045\(16\)30510-1](http://dx.doi.org/10.1016/S1470-2045(16)30510-1)
16. Innovation in oncology clinical trial design. <https://doi.org/10.1016/j.ctrv.2019.01.001>
17. Challenges with Novel Clinical Trial Designs: Master Protocols. <https://aacrjournals.org/clincancerres/article/25/7/2049/82445/Challenges-with-Novel-Clinical-Trial-Designs>
18. Design and Evaluation of an External Control Arm Using Prior Clinical Trials and Real-World Data. <https://aacrjournals.org/clincancerres/article/25/16/4993/125037/Design-and-Evaluation-of-an-External-Control-Arm>
19. Protocol-in-a-Day Workshop: A Lean Approach to Clinical Trial Development and Focus on Junior Faculty Development. [https://www.advancesradonc.org/article/S2452-1094\(19\)30018-1/fulltext](https://www.advancesradonc.org/article/S2452-1094(19)30018-1/fulltext)
20. Accomplishing an adaptive clinical trial for cancer: Valuation practices and care work across the laboratory and the clinic. <https://pubmed.ncbi.nlm.nih.gov/32278242/>
21. Designing Dose-Finding Phase I Clinical Trials: Top 10 Questions That Should Be Discussed With Your Statistician. <https://ascopubs.org/doi/full/10.1200/PO.20.00379>
22. Patient-Reported Outcome Measures in Clinical Research. <https://jamanetwork.com/journals/jama/article-abstract/2794492>

***NOTE: A supplemental reading list can be found [here](#).