Discipline MCP5895
Critical Analysis of Heart Failure Research

Concentration area: 5131

Creation: 11/03/2021

Activation: 07/07/2021

Credits: 2

Workload:

Theory (weekly)	Practice (weekly)	Study (weekly)	Duration	Total
8	20	2	1 weeks	30 hours

Professors:

Edimar Alcides Bocchi

Silvia Moreira Ayub Ferreira

Vera Maria Cury Salemi

Objectives:

Formation of human resources with research planning capacity with consequent publication for the scientific quality of the research and submission in an appropriate manner to the scientific journals with the greatest impact.

Rationale:

One of the biggest limitations to the success of graduate programs is the difficulty of publishing scientific articles resulting from graduate theses in scientific journals of greater prestige and impact. The main reasons for the challenge of publishing in scientific journals with the greatest impact are the quality of the research result and the form of preparation / submission of the resulting manuscript. The program of this course will consist of strategies for an adequate planning of the research and adequate preparation of the manuscript aiming at accuracy for submission in a prestigious magazine and greater impact with success. In planning the development of research and methodology, this will be the subject of classes / presentations / seminars aimed at subjects of high relevance and adequate design to obtain innovative results for science and clinical practice, contributing to the development of the country. The complex aspects of research planning will be addressed in such a way as to be accessible to students or candidates for the postgraduate course. In planning the preparation of the manuscript, students will be able to receive guidance and participate in classes / presentations / seminars including topics such as choosing the appropriate journal, presenting the manuscript properly, analyzing and presenting the results, interpreting the results and their implications, balanced and based discussions evidence and appropriate titles.

Content:

Theoretical classes 1. “Systematic” bibliographic review of published studies, records, and meta-analyzes on the hypothesis to be tested. How to analyze and judge published data. Is the hypothesis innovative and original? 2. How to interpret the results of previous studies for innovative and relevant research. 3. CONSORT 4. Choice of relevant and innovative

hypotheses. Feasibility of the study. 5. Basic notions of scientific methodology: types of research (cross-sectional, case-control, cohort, randomized studies), benefits and risks associated with research, legal rules for research in humans and laboratory animals. 6. Research protocol: material (configuration of the study population, inclusion and exclusion criteria), consent form, Research Ethics Committee, limitations. 7. Questionnaires: how to describe an objective (primary and secondary), sample selection techniques, sample size calculation, discrepant data. Avoid Type I and Type II Errors. 8. Basic points of experimentation (I): technical terms, study of the effect of a treatment, positive control, comparative studies, historical controls. 9. Basic points of experimentation (II): dose-response study, wash-out, follow-up, how to use the individual as your own control. 10. Observational studies: definition, case control study, cohort study, a factor can be clinically important and not statistically important, a factor can be statistically and non-clinically important. Retrospective studies. Prognostic studies. Prospective population studies. Advantages and disadvantages. 11. "Trials": experimental design, superiority vs equivalence, recruitment, randomization (similar distribution of factors), subgroup analysis, secondary outcomes, intention-to-treat analysis (randomized treatment) vs on treatment (received treatment), multicenter studies vs unicentric. 12. Characteristics of high impact studies. Randomization, the control group, the "sham", the blind study. Execution of the study. Importance of accuracy. Adequate follow-up time? Basic statistics. 13. How to analyze results carefully. The p value. Potential explanation for the results. Causality versus association. "Limitations of surrogate end-points". Relationship of "surrogated-endpoints" with "hard-endpoints". How it differs from other studies. Statistical difference versus clinical importance. MID. 14. Definition of authorship of scientific article publication according to the ICMJE International Committee of Medical Journal Editors (http://www.icmje.org). Conflict of interest. How to avoid: plagiarism, "salami", inappropriate authorship, duplicate or multiple submission, duplicate data, "overlapping", errors or manipulation in figures. 15. How to prepare a manuscript well. Guidance, for title, summary, introduction, rationale, definition of objectives, objective methodology in detail, validity of the methodology, accuracy, reproducibility, results, discussion, implications, and conclusions. Emphasize what is innovation or originality, "first" or "definitive" data where there is controversy. If it is a study with a larger population or an incremental or confirmation study for the selected population, adequately define the results in relation to the objective. Manuscript size. Number of tables and figures. 16. Researchers' performance evaluation methods and scientific articles. Workshops 1. Discussion on randomized studies (CONSORT: guidelines for reporting parallel group randomized trials) based on a scientific article. (https://www.equator-network.org/reporting-guidelines/consort/). 2. Discussion of study protocols (SPIRIT: Standard Protocol Items Recommendations for Interventional Trials) based on a scientific article. (Http://www.spirit-statement.org/). 3. Discussion on observational studies (STROBE: STrengthening the Reporting of OBservational studies in Epidemiology) based on a scientific article. (https://www.strobe-statement.org/index.php?id=strobe-home/). 4. Discussion on Systematic Review and Meta-Analysis (PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyzes) based on a scientific article. (http://www.prisma-statement.org/). 5. Discussion on diagnostic studies (STARD: Essential Items for Reporting Diagnostic Accuracy Studies) based on a scientific article. (https://www.equator-network.org/reporting-guidelines/tripod-statement/). 6. Discussion of prognostic studies (TRIPOD: transparent reporting of a multivariable prediction model for individual prognosis or diagnosis) based on a scientific article. (https://www.equator-network.org/reporting-guidelines/stard/). 7. Discussion of clinical case studies (CARE: Consensus-based Clinical Case Reporting Guideline Development) based on a scientific article. (https://www.equator-network.org/reporting-guidelines/care/). 8. Discussion on clinical practice guidelines (AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines) based on a scientific article. (https://www.equator-network.org/reporting-guidelines/the-agree-reporting-checklist-a-tool-to-improve-reporting-of-clinical-practice-guidelines/). 9. Discussion on qualitative research (SRQR: Standards for reporting qualitative research: a synthesis of recommendations and COREQ: Consolidated criteria for reporting qualitative research) based on a scientific article. (https://www.equator-network.org/reporting-guidelines/srqr/), (https://www.equator-network.org/reporting-guidelines/coreq/). 10. Discussion on preclinical studies (ARRIVE: Animal Research: Reporting of In Vivo Experiments) based on a scientific article. (https://www.equator-network.org/reporting-guidelines/improving-bioscience-research-reporting-the-arrive-guidelines-for-reporting-animal-research/). 11. Discussion on qualitative improvement studies (SQUIRE: Standards for QUality Improvement Reporting Excellence) based on a scientific article. (https://www.equator-network.org/reporting-guidelines/squire/). 12. Discussion on economic assessments based

on a scientific article (CHEERS: Consolidated Health Economic Evaluation Reporting Standards). (Https://www.equator-network.org/reporting-guidelines/cheers/).

Type of Assessment:

Use and participation during classes and discussions (the responsible teachers encourage and are present in all classes).

Bibliography:

1. DeMaria A. How do a get a paper accepted ? JACC 2007;49:1666-1667. 2. DeMaria A. How to get a paper accepted ? part 2. JACC 2007;49: 1989-90 . 3. Swedberg K Who is an author. Eur J Heart Failure 2008;10:523-24. 4. Swedberg K. How to publish in European Journal of Heart Failure. Eur J Heart Failure 2008;2008;10:1-2. 5. DeMaria NA. What constitutes a great review ? JACC 2003;42:1314-11315. 6. DeMaria AN. Clinical trials and clinical judgment.JACC 2008;51:1120-1122. 7. Brown CH, Kellam SG, Kaupert S, Muthén BO, Wang W, Muthén LK, Chamberlain P, PoVey CL, Cady R, Valente TW, Ogihara M, Prado GJ, Pantin HM, Gallo CG, Szapocznik J, Czaja SJ, McManus JW. Partnerships for the design, conduct, and analysis of effectiveness, and implementation research: experiences of the prevention science and methodology group. Adm Policy Ment Health 2012;39:301-16. 8. Costa R, van Leeuwen TN, van Raan AFJ. The "Mendel syndrome" in science: durability of scientific literature and its effects on bibliometric analysis of individual scientists. Scientometrics 2011;89:177-205. 9. Vieira S, Hossne WS. Metodologia científica para a área de saúde. Rio de Janeiro: Elsevier, 2001  13a impressão. 10. Lader EW, Cannon CP, Ohman EM, Newby LK, Sulmasy DP, Barst RJ, Fair JM, Flather M, Freedman JE, Frye RL, Hand MM, Jesse RL, Van de Werf F, Costa F; American Heart Association. The clinician as investigator: participating in clinical trials in the practice setting: Appendix 1: fundamentals of study design. Circulation. 2004;109:e302-4. 11. Parker AB, Naylor CD. Subgroups, treatment effects, and baseline risks: some lessons from major cardiovascular trials. Am Heart J. 2000;139:952-61. 12. Pocock SJ, Stone GW. The primary outcome is positive. Is that good enough ? N Engl J ed 2016;375:971-9. 13. Pocock SJ, Stone GW. The primary outcome fails. What next ? N Engl J ed 2016;375:861-70 14. Pocock SJ, McMurray JJV, Collier TJ. Making senses os statistics for clinical trials. JACC 2015;66:2536-2549. 15. Moye L. Statistical methods for cardiovascular researchers. Circ Res 2016:118:439-453. 16. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, Lancaster GA; PAFS consensus group. CONSORT 2010 statement: extension to randomised pilot and feasibility trials.Pilot Feasibility Stud. 2016 Oct 21;2:64. eCollection 2016.