**Clinical Research Manuscript**

**Typical Format and Key Considerations for Each Section**

Typical format of a clinical research manuscript

The format, including section names, may vary based on the journal. It is essential to review the journal’s guide for authors before formatting your manuscript. Most journals use the IMRAD format (Introduction, Methods, Results, and Discussion) for the core of the manuscript.

1. Title
2. Abstract
3. Introduction
   1. The issue/problem (what is known?)
   2. Gaps in the literature (what is not known?)
   3. Objectives and hypothesis (how does the study address what is not known?)
4. Methods
   1. Ethical approval
   2. Study design, setting, and timing
   3. Study population
   4. Intervention/study groups
   5. Data collection and validation
   6. Statistical analysis plan
5. Results
   1. Descriptive statistics of the study population
   2. Procedural results and outcomes
   3. Results of the statistical analyses
6. Discussion
   1. Synopsis of the main findings
   2. Interpretation of the findings
   3. Interpretation in the context of the literature, including clinical implications
   4. Strengths and limitations
   5. Summary and future directions
7. References
8. Acknowledgements
9. Conflicts of interest

Key considerations for each section

1. Title
   * The purpose is to clearly and succinctly capture the main finding of the research.
   * Aim to use less than 100 characters/15 words.
   * Avoid acronyms, abbreviations, and jargon.
   * Consider using keywords which allows for easier discovery of the manuscript with search.
2. Abstract

* The purpose is to briefly summarize the study’s objectives, methods, results, and conclusions.
* Aim to be complete and concise, providing a stand-alone description of the research and the take-home message.
  + Avoid providing any information that is not presented in the remaining sections of the manuscript.
  + Consider writing the abstract last.
  + The word limit is journal specific (refer to the journal’s guide for authors).

1. Introduction
   * The purpose is to provide background information on the topic, highlight the gaps in the literature, and describe the study objectives.
   * Consider following a 3 paragraph format that is structured as a funnel, moving from a broader perspective on the topic and finishing with a narrow focus on the study.
     + What is known about the issue? Why is it important?
     + What is not known about the issue?
     + What is the objective of the study? What does it add to the existing knowledge?
   * Use the present tense, as this section generally presents accepted facts and principles.
   * The typical length is about 350 words.
2. Methods
   * The purpose is to thoroughly describe the study design, procedures, and tools used for data collection and analysis.

* Use the study protocol as a guide for completing this section.
* Describe the study in chronological order, providing enough detail so that an investigator in the field could replicate the study. This includes:
  + Statement about ethical approval and informed consent
  + Study design, setting, and timing
  + Study population, including recruitment, inclusion and exclusion criteria, and, if applicable, the randomization process
  + Intervention details, including detailed description of treatment groups
  + Data collection, including origins of samples, and use of validated surveys, instruments, and methodologies (include references)
  + Statistical analysis plan, including power analysis, the statistical analysis of the primary outcome, followed by a description of the analysis of secondary outcomes, and the software used for analysis
* Use the past tense to describe what was done.
* The typical length is < 1,000 words, but it may be shorter for simple lab studies and longer for studies involving a new methodology.

1. Results
   * The purpose is to describe the study findings.
   * Avoid including background information or interpreting the results.
   * Organize this section in parallel with the organization of the methods section, with every method described having a corresponding result.
   * Focus on the visual presentation of the findings in figures and tables.
     + They should follow the order in which they are presented in the text, with the first table describing the study population.
     + Figures and tables should highlight key findings and be able to stand alone without explanatory text.
   * Start by describing your population, including how many subjects, how many protocol failures, demographics of the study groups, etc.
   * Describe the outcome of the primary variable followed by the outcomes of the secondary variables.
   * Use the past tense to describe what was found.
   * The typical length is about 350 words.
2. Discussion
   * The purpose is to interpret the results, and explain their clinical implications and how they fit within the existing knowledge.
   * This section takes the shape of a reverse funnel, starting with the narrow focus of the research findings and moving towards a broader perspective on the topic.
     + Start with a brief synopsis of the main findings to orient the reader, using about 3 sentences that are focused on answering the research question.
     + Provide the rationale for the chosen study design/approach (e.g., justify the protocol, inclusion criteria, design) and its importance compared to existing studies.
     + Place the findings in the context of what other studies have found and how they relate to your findings, pointing out differences and similarities in the results.
     + Discuss the clinical significance of the findings.
     + Describe the strengths and limitations of the study, and elaborate on the implications of the limitations.
     + End with a final conclusion, which succinctly summarizes the main findings and suggests future research directions.
   * Avoid covering up any results that are inconsistent with the literature, and overstating the findings or providing a speculative conclusion.
   * This section may be written in the past, present, or future depending on the context.
3. References
   * Lists all the sources cited in your paper.
   * Be sure to carefully read any study you reference to ensure it is sited appropriately, keeping in mind that your reviewers are likely to be the authors of your references.
   * Aim to cite the original source(s) behind any key statement.
   * The reference format is journal specific (refer to the journal’s guide for authors).
4. Acknowledgements
   * This section is typically used to thank the funding agency.
   * It may also be used to acknowledge people who helped with the development of the work, such as technicians.

**References:**

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