

The Milestones of Clinical Research for Young Generalist Physicians: Conducting and Publishing Studies

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Abstract: Clinical physicians have the potential to contribute to the progress of medicine and healthcare through research based on their diagnostic and treatment practices and supported by their educational background. However, in the field of general medicine in Japan, publication of such research in international journals may be limited by challenges in English proficiency and the lack of opportunities to focus on specific research themes amidst the diverse range of diseases treated in clinical practice. Furthermore, novice researchers without prior research experience may lack a comprehensive understanding of the overall research process, including study design and article publication. To address these challenges, we developed a set of 22 milestones that highlight the necessary skills required to conduct and successfully publish clinical research. This guideline will enable novice researchers to identify and address individual barriers to undertaking a research project. These milestones are categorized into five parts: 1) preparing to undertake research; 2) conducting clinical research; 3) writing the article; 4) submitting and achieving acceptance for publication; and 5) advanced skills. For each part, we provide detailed recommendations on the specific steps and methods involved. By working through these 22 milestones, novice researchers can objectively assess their own level of achievement as researchers and continuously clarify the next step of each round of research. Through this set of milestones, we aim to increase the quality and quantity of research publications in general medicine in academic journals, ideally enhancing the overall research process and advancing the field of medicine and healthcare overall.

Keywords: clinical research, original research, young physicians

Physicians are expected to conduct research in diverse clinical and educational settings and to disseminate their findings to advance the field of medicine and healthcare.¹⁻³ However, novice researchers may encounter barriers to completing their research endeavors, encountering internal resistance to performing clinical research or lacking a clear understanding of the necessary steps, even when motivated.² More specifically, novice researchers may struggle with common challenges, including uncertainty about how to initiate the research process, time constraints, difficulties securing funding, lack of mentorship, insufficient knowledge of how to write research articles, and communication barriers for non-native English speakers.^{2,4,5} These issues are often too complex for novice researchers to articulate clearly, which can lead to a vague sense of unease or apprehension that impedes their ability to identify and address these challenges effectively. The uncertainty of whether a paper will be accepted for publication can discourage busy clinical doctors, who have a heavy workload, from taking the time necessary to engage in writing a research paper.⁴ As a result, many novice researchers struggle with how best to overcome these barriers and move forward with their research goals.

In the field of general medicine in Japan, only 3.8% of the research presented at academic conferences is subsequently published,⁶ which is significantly lower than the reported rate of approximately 40% in other countries.⁷ This low percentage of English-language research articles may be attributed to the fact that general medicine is a relatively new field in Japan and

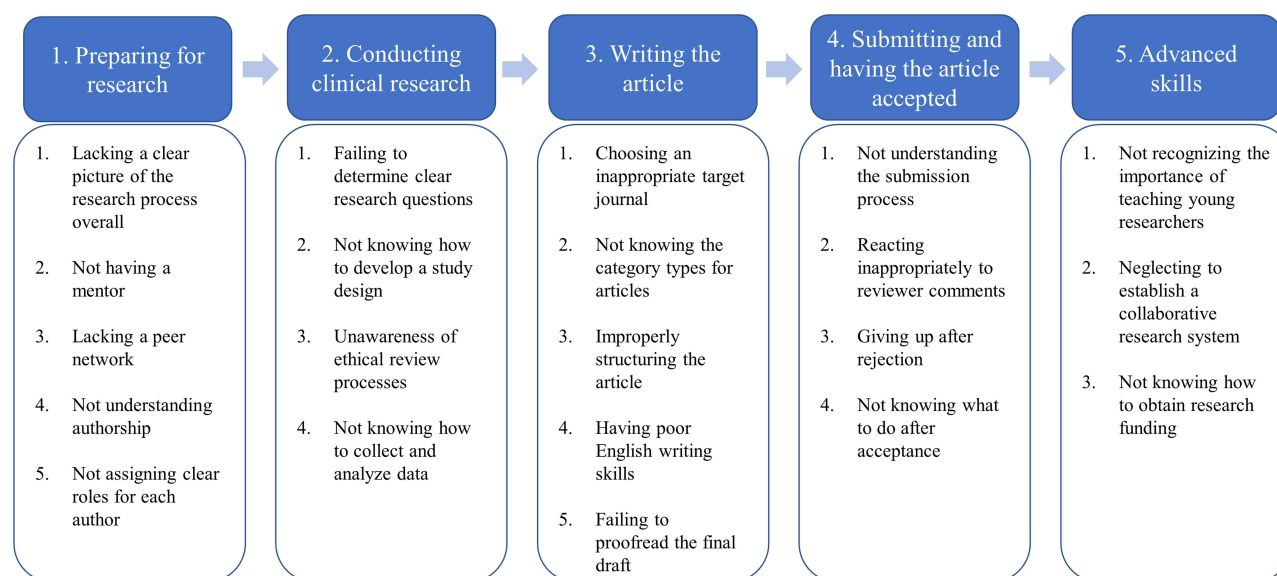


Figure 1 Factors that contribute to failure in clinical research.

was included in the new medical specialty system (as the 19th specialty) for the first time in 2018.⁸ Furthermore, researchers whose native language is Japanese face a communication barrier that may also contribute to the low number of research articles published in English.⁶ Moreover, the field of general medicine encompasses a diverse range of diseases and backgrounds, making it challenging for those conducting research for the first time to focus on a specific research topic.

Understanding the manuscript submission process is crucial, as research indicates that students who are familiar with it are more likely to have their articles published than those who are not.⁹ However, novice researchers often lack such knowledge because of insufficient educational opportunities related to research. Having a mentor or a colleague who can provide guidance and advice is particularly important,^{10,11} but clinical physicians may not always have access to experienced mentors. Therefore, it is necessary to provide strategies to help novice researchers overcome challenges independently. To this end, we analyzed and categorized the factors that contribute to failure in clinical research, as shown in Figure 1. Based on this analysis, we created a set of milestones for conducting and successfully publishing clinical research that also outlines the common problems to be addressed and the necessary skills to be acquired (Table 1). This will allow novice researchers to break larger challenges into specific manageable steps and to identify actionable steps to address the challenges. In this article, we provide a detailed explanation of each item in the set of milestones.

Prepare for Research

- (1) Ensure that you first understand the processes involved in conducting clinical research.
- (2) Seek advice and guidance from an experienced physician (mentor theory).
- (3) Assess whether the experienced physician is suitable for the specific research project (mentor theory).
- (4) Collaborate with colleagues on research projects.
 1. Explain the criteria for authorship.
 2. Clarify the roles and responsibilities of co-authors.

To begin, novice researchers should clearly understand the overall process of clinical research and publication. As detailed in the Table 1, clinical research progresses through stages of study preparation, conducting experiments and/or collecting and analyzing data, and writing the article. Once the researcher has a solid grasp of these stages and can navigate them successfully, they can progress to the advanced stage of conducting more complex research and supervising others.

Table 1 The Milestones of Clinical Research and Publication

[1]	Prepare for research
1	Ensure that you first understand the processes involved in conducting clinical research
2	Seek advice and guidance from an experienced physician (mentor theory)
3	Assess whether the experienced physician is suitable for the specific research project (mentor theory)
4	Collaborate with colleagues on research projects 1. Explain the criteria for authorship 2. Clarify the roles and responsibilities of co-authors
[2]	Conduct clinical research
5	Planning 1. Identification of the research problem 2. Carry out a literature review 3. Formulate a research question
6	Development 1. Study design 2. Study proposal 3. Ethics and operational approval
7	Operation 1. Data collection 2. Data cleaning and analyses 3. Write up study results
8	Summary and interpretation of results 1. Summarize and interpret the results 2. Discuss the implications of the study and draw conclusions
[3]	Write the research article
9	Understand the format of a research article 1. Narrow down the target journal options 2. Adopt the custom format required by the target journal
10	Break down the process of writing a research article 1. Write the Conclusion section 2. Write the Results section 3. Write the Methods section 4. Write the Discussion section 5. Write the Introduction section 6. Write the Abstract 7. Create the list of References 8. Create the list of Acknowledgments and other sections 9. Create the Title Page 10. Write a Cover Letter
11	Proofread the final draft of the English text to correct spelling, grammatical, and typographical errors
[4]	Submit an article and achieve acceptance for publication
12	Follow the submission guidelines
13	Understand the post-submission process
14	Respond appropriately to reviewer comments
15	Revise the manuscript
16	Resubmit the manuscript

(Continued)

Table 1 (Continued).

	In case of rejection
17	Respond to rejection quickly and appropriately
18	Revise and resubmit the manuscript multiple times, as necessary
19	Effectively promote the significance and novelty of the research
[5]	Advanced skills
20	Provide research guidance
21	Establish collaborations with research partners
22	Gain knowledge about how to write successful research proposals and grant applications to secure research funding

At the start of their research journey, novice researchers should seek a mentor to guide them through the entire research process, from developing research questions and designing studies, to writing manuscripts.¹⁰ Finding a mentor with compatible values and work attitudes is crucial, as this will affect the quality of the mentor–mentee relationship. If no suitable mentors are available in the immediate environment, viable options for finding a mentor include attending conferences and lectures related to individual research interests, and contacting active researchers in the field. Seeking advice from senior physicians with accomplished records in research and publication is a good option when help is needed, even if such physicians cannot serve as mentors per se. The COVID-19 pandemic has led to a significant shift toward online communication, and remote mentoring is more common than ever before.¹² Therefore, regardless of physical distance, adopting a proactive attitude toward learning and building good relationships with potential researcher-mentors, are crucial. Additionally, given the complexity of clinical research, it is almost impossible for a novice researcher to conduct research alone. Therefore, in addition to finding a mentor, they must build a research peer group or team. When conducting research with multiple researchers, it is essential to establish clear criteria for authorship. The International Committee of Medical Journal Editors defines authorship as follows: “Authorship confers credit and has important academic, social, and financial implications”.¹³ All study authors are also responsible for various aspects of the research process, including study conception, data collection, interpretation of results, and manuscript writing.¹³

Conduct Clinical Research

(5) Planning

1. Identification of the research problem
2. Carry out a literature review
3. Formulate a research question

(6) Development

1. Study design
2. Study proposal
3. Ethics and operational approval

(7) Operation

1. Data collection
2. Data cleaning and analyses
3. Write up study results

(8) Summary and interpretation of results

1. Summarize and interpret the results
2. Discuss the implications of the study and draw conclusions

The development of research questions and design of a study are considered the most crucial aspects of the research process, and can often determine its success or failure.^{14,15} However, novice researchers sometimes struggle

to identify a specific research topic or question. In such cases, it may be helpful to write down unanswered questions related to the epidemiology, symptoms, and diagnoses of diseases that they encounter regularly, and subsequently review the relevant literature to aid in pinpointing a research question. Additionally, attending conferences and lectures, and reading general medicine journals, can help novice researchers develop their interests in the field and gain knowledge on current topics. Given the wide range of diseases and diversity of patient backgrounds in general medicine, focusing on a specific research topic can be challenging for novice researchers. However, the wide range of study areas available to generalists provides ample opportunities to generate research questions. These study areas include diagnostic excellence, clinical epidemiology, symptomatology, home and community medicine, education, hospital operation and management, public health and preventive medicine, and physical examination.^{16,17} Once researchers have identified a number of research questions, choosing the most compelling one will create the motivation to pursue the research. At the same time, when choosing research questions, it is important to prioritize the following: 1) conduct research that is relevant to the field of practice or policy; 2) fill gaps in the current knowledge; and 3) provide timely and essential knowledge that can contribute to a specific field. The next step involves formulating a hypothesis about the expected outcome,¹⁴ determining the feasibility of studying the outcomes (eg, qualitative or quantitative evaluation, testable hypothesis),¹⁸ and conducting a thorough literature review to identify previous studies.¹⁴ The authors also need to demonstrate that their research will contribute to the literature in the specific area.

To conduct a research study, researchers need to have a solid understanding of research methodology, which involves developing a study design, collecting and analyzing data, and interpreting results. Novice researchers can improve their knowledge in this area by reading published articles and textbooks on research design and the research process in general. However, one of the challenges for novice researchers is finding previous studies related to their research questions. To address this issue, they should rely on secondary literature sources, such as review articles and textbooks, or use popular search engines, such as Google. As they become more familiar with literature searching, they can also use keyword searches to locate relevant articles.¹⁹ An effective strategy for identifying relevant articles is to search using multiple keywords of interest in databases such as Google Scholar and PubMed, and to search for articles cited in review articles. Specifically, PubMed's MeSH (Medical Subject Headings) search feature can help researchers find articles using a set of common keywords. Additionally, artificial intelligence-based search services have emerged in recent years, making it easier to find target articles.

Ethical considerations are essential when planning and conducting medical research. Ethical guidelines have been established for various fields, and include the Nuremberg Code and the Helsinki Declaration.²⁰ Researchers must ensure fairness and safety in all studies, obtain informed consent, and protect the participants' personal information and dignity. Furthermore, they should consider potential ethical issues, submit their research proposals to an ethics committee, and obtain approval before conducting the study.²¹ Once the research proposal is ready, high-quality, reproducible data must be collected and analyzed. To ensure data quality, it is necessary to clearly define the items, check for missing or inconsistent data, and perform data cleaning procedures, such as standardization of collected data.²² To learn about analysis methods, novice researchers can refer to textbooks and published studies, solicit guidance from mentors, and utilize free websites or video streaming platforms that explain basic principles and methods of statistical analysis. Workshops on statistics and data analysis (free and paid) are also available, making it possible to efficiently learn these essential skills. When conducting a literature review, novice researchers should ensure that they understand the logic and statistical methods applied in previously published studies to adequately address the research questions posed there. They need to summarize the results of previous studies and interpret the significance of their findings.

Write the Research Article

(9) Understand the format of a research article.

1. Narrow down the target journal options.
2. Adopt the custom format required by the target journal.

- (10) Break down the process of writing a research article.
 1. Write the Conclusion section.
 2. Write the Results section.
 3. Write the Methods section.
 4. Write the Discussion section.
 5. Write the Introduction section.
 6. Write the Abstract.
 7. Create the list of References.
 8. Create the list of Acknowledgments and other sections.
 9. Create the Title Page.
 10. Write a Cover Letter.
- (11) Proofread the final draft of the English text to correct spelling, grammatical, and typographical errors.

It is desirable to decide on a target journal before starting to write a research article, as some journals have different limitations on word count and the types of manuscripts that are accepted (original research, review, commentary, etc.). After identifying multiple potential target journals, it is recommended to confirm the readership and specialized fields that each journal covers, as well as other factors, including open access availability, acceptance rate, impact factor, cost, and presence of a peer review system. Additionally, published articles from the target journal can serve as concrete style samples, greatly assisting the writing process.

Original research articles typically follow a standard structure comprising five sections: Introduction, Method, Results, Discussion, and Conclusion.^{23,24} To effectively convey the main message to readers, first draft the Conclusion that will be argued, based on the research question, hypothesis, and results. Because the conclusions should be clearly worded statements derived from the background, research results, and discussion, authors should first describe the current situation based on a thorough literature search, using that as a foundation to construct clear discussions in other sections. Subsequent sections should be written in the order of Results, Methods, Discussion, and Introduction. In the Results section, the analyzed results are presented in an objective and concise manner, without the authors' interpretations.^{23,24} To create a concise, understandable Results section, tables and figures that illustrate the analytical procedures and results should be crafted before the body of the Results section is written, together with brief explanations that help readers understand the content of each.²⁴ The points to be discussed in each section are then outlined. In the Methods section, the data collection and analysis methods should be objectively and thoroughly described, such that other researchers could replicate the study.^{23,24} For example, it is essential to: use objective indicators for items to be measured and outcomes; establish clear outcomes; and thoroughly consider confounding factors and biases. Additionally, following guidelines such as the CONSORT statement for randomized controlled trials, the CARE statement for case reports, and the STROBE statement for observational studies can help authors to establish the most appropriate methods.²⁵ In the Discussion section, the research results should be compared with relevant literature, stating the interpretations of what has been revealed and how the results differ from previous studies.²³ Especially for novice researchers, it is recommended to carefully interpret the meaning of the results and thoroughly evaluate their effectiveness, limitations, and significance. Key elements of the Discussion section include the authors' research results and claims, a comparison of previous research with the authors' results, limitations of the study, and future prospects.²⁴ Additionally, it is recommended to examine how the results obtained from a study emphasize the significance and relevance of other evidence by comparing the research objectives and hypotheses. The authors should describe how their research contributes important knowledge beyond that gained in prior studies and emphasize that the overarching goal is to expand the knowledge base regarding their specific area of clinical care or health care policy. In the Introduction section, the authors should present background information related to their research, highlighting any unverified or unclear areas that make the study necessary, and clearly stating the purpose of their research as a research question at the end.²³ The Title and Abstract are the first parts of a research article that readers encounter, and their significance should not be overlooked.²³ Therefore, it is recommended to write the Abstract at the end of the article writing process.²³ If the Abstract is written first, it is crucial to reconfirm its appropriateness after finishing the body of the article.²⁴ Before submission, a list of References, Acknowledgments, Conflicts Of Interest statement, and Title Page should be created following the journal's submission

guidelines. The Cover Letter, which is addressed to the Editor of the target journal, highlights the Title and critical points of the authors' study and requests publication. Using a mentor's previous cover letter as a guide is a simple way to create one; alternatively, there are companies that provide proofreading and editing services for cover letters written by non-native English speakers.

Submit an Article and Achieve Acceptance for Publication

- (12) Follow the submission guidelines.
- (13) Understand the post-submission process.
- (14) Respond appropriately to reviewer comments.
- (15) Revise the manuscript.
- (16) Resubmit the manuscript.

In case of rejection:

- (17) Respond to rejection quickly and appropriately.
- (18) Revise and resubmit the manuscript multiple times, as necessary.

After acceptance:

- (19) Effectively promote the significance and novelty of the research.

The process of submitting an article differs from journal to journal, but the post-submission process is generally the same. Once submitted, an article undergoes peer review, and the Editor makes a decision based on the comments provided. A point-by-point response to the peer review comments is necessary if revisions are requested. It is important to approach the response to all peer review comments with respect and sincerity. It is natural to aspire to submit one's article to a high-impact journal, but the acceptance rate of peer-reviewed academic journals averages between 19% and 62%,²⁶ and rejection is common. While rejection may elicit negative feelings, resubmitting the article quickly to another target journal is essential. Before the initial submission, one should carefully contemplate whether the article's content aligns with the target journal's scope,²⁷ and pre-select multiple potential target journals. Even if the article is rejected, peer review comments may lead to quality improvements, and addressing essential comments before resubmission can increase its chances of acceptance. If there are no reviewer comments, or the comments are unhelpful, revisions should be made following the submission guidelines of the next target journal.

Once the article has been accepted and published, it is crucial to utilize social media and institutional websites to promote the highlights and most exciting aspects of the research, and potentially attract the interest of many individuals. If the research reaches the eyes of those who are interested in the study subject or theme, its significance will rise, enabling it to contribute to the future advancement of medicine.

Advanced Skills

- (20) Provide research guidance.
- (21) Establish collaborations with research partners.
- (22) Gain knowledge about how to write successful research proposals and grant applications to secure research funding.

As researchers begin to conduct multiple studies and publish articles, it is crucial that they gain an educational perspective on the value of nurturing future researchers while simultaneously carrying out their own research. As mentors, not only can they explain the significance of research to their mentees, they can conduct research together and co-author articles, thereby fostering the research mindset.²⁸ Additionally, increasing the number of individuals capable of conducting research can lead to increases in organizational and personal research achievement, as well as clinical experience in the field.²⁸

Multicenter studies are much more challenging than single-center studies for many reasons, including the involvement of multiple facilities, different data formats and quality, cultural differences between hospitals, differences in the quality, research mindset and motivation of medical staff (including doctors), and management of human resources.²⁹ Additionally, a significant amount of funding is required for expenses, such as personnel costs and facility adjustments.³⁰ Furthermore, as the number of people involved in a multicenter study increases, more coordination is required between each facility, further increasing the administrative burdens. Therefore, roles and responsibilities within the research team must be clearly defined, and include training others in research procedures, data extraction and analysis, and budget and paperwork. To improve the inter-evaluator reliability of data and the reproducibility of the study, researchers need to discuss, define, and communicate the research objectives and data collection items before starting the study, and regularly throughout the study. Practical communication skills and strong leadership are essential for co-researchers to fulfill their roles.

Finally, research commonly requires significant financial expenditures, such as personnel costs, material costs, maintenance costs, English proofreading fees, and publication fees. With funding, efficient results can be achieved by outsourcing the collection, cleaning, and analysis of data. Additionally, funding can broaden the scope of research, increase feasibility of projects, enable the development of research methods, and expand the scale of research, by increasing the number of research facilities or study participants, for example. Obtaining funding to conduct high-quality research, whether at a university or a community hospital, requires applying for research grants from government agencies, companies, and other research funding organizations. While obtaining external funding is not easy, it is important to continuously seek research grant awards by presenting the results of one's preliminary research, demonstrating the societal significance and importance of the research, and clearly communicating one's research abilities and the feasibility of the proposed research.

Conclusion

Novice researchers can objectively assess their level of achievement as researchers and clarify next tasks by checking their progress against these 22 milestones. Additionally, these milestones can guide learning about the overall research and publication process, and will hopefully lead to the publication of more research in various fields of general medicine.

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Author Contributions

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