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PEER REVIEWED

Utilization of Real-World Data to Enhance Recruitment and Retention of Clinical Research Participants

Patrick Sturges, MS, CCRP

The success of a clinical trial depends on a myriad of factors, but none is more important than the clinical research participants. Optimized patient participation, achieved with effective recruitment and retention planning, is a key component to any successful clinical trial. With the emergence of real-world data (RWD) utilization in clinical research, achieving effective recruitment and retention is more plausible than at any other time in the field of clinical research. RWD facilitate a better understanding of the available patient population and improved protocol design. Consequently, recruitment and retention planning is streamlined to allow for optimized patient participation, enhanced adherence to enrollment windows, and close attention to budget parameters.

Background

Recruitment and retention of clinical trial participants are the cornerstones of any clinical trial; in the absence of either one, a clinical trial will fail. A clinical trial's failure as a result of ineffective recruitment or retention is both an impediment to advances in the treatment of disease and a massive financial burden. A clinical trial unable to recruit or retain subjects cannot acquire the necessary data to support the statistical analysis of the endpoints, which renders the trial meaningless.

In addition, failure to recruit and retain clinical trial participants results in wasted time and money. Based on a previous review of hundreds of clinical trials on ClinicalTrials.gov, 39% of the trials were closed prematurely due to issues with recruitment and retention.{1}

According to data from a recent publication, recruitment/enrollment of clinical trial participants accounts for 32% to 40% of a clinical trial's budget.{2} Allocation of such a significant portion of the clinical trial budget to recruitment is primarily associated with the frequent requirement to extend recruitment/enrollment windows beyond original estimates.{2} Although ineffective recruitment and retention are caused by a variety of factors, many can be addressed (and potentially eliminated) with enhanced clinical trial planning via utilization of RWD.

RWD are healthcare-related data derived from sources not associated with clinical trials.{3} RWD can include data from electronic health records, physician notes, tumor registries, insurance claims, and mobile devices and/or wearables.{3} RWD encompass a wide area of data, and the key to their utilization is the overall integration of the various sources of the data. The future of healthcare is in sharing of RWD and ensuring a seamless integration of all the platforms where the data are housed.

Taking a Deeper Dive

The effectiveness of recruitment and retention is influenced by numerous factors. For the purposes of this article, the most impactful factors will be discussed. First, clinical trial participation among adults ranges from 5% to 10% across most therapeutic areas, and participation for older adults is as low as 3%.{4,5} Therefore, there is a vast population of potential clinical trial participants left unrecruited into clinical trials.

Second, clinical trial protocols are too complex—the inclusion/exclusion criteria are too restrictive, data are being collected for endpoints having no bearing on the critical endpoints of safety and effectiveness, and there are too many required patient visits, blood draws, and additional tests.{6}

Third, which is linked to protocol complexity, frequent protocol amendments and subsequent re-consenting (when required) negatively impact patient recruitment and retention.{6}

Fourth, the sample size for many clinical trials is typically quite large as compared to the study population being examined. In some instances, clinical trials are either overpowered (more clinical trial participants targeted than needed to achieve statistical significance) or target a larger than necessary recruitment number to support secondary endpoints.{7}

Optimizing the process of recruiting and retaining clinical research participants is a primary focus of stakeholders in the arena of clinical research. In view of the impediments to advances in treatment of

disease caused by the wasted time and financial burden resulting from ineffective recruitment and retention, stakeholders are examining methods to improve upon the situation.

Methods currently being explored by stakeholders include:

- Leveraging RWD (the focus of this article)
- Enhancing patient engagement throughout the entire life cycle of a clinical trial (from design to inception to regulatory and market approval)
- Utilization of digital and social media platforms and artificial intelligence and machine learning

It is an exciting time in clinical research with the merging of precision medicine and digital healthcare, coupled with enhanced patient engagement.

The Shape of Things to Come?

In a March 2019 U.S. Food and Drug Administration (FDA) statement,{8} then-Commissioner Scott Gottlieb, MD, discussed the need to modernize clinical trials due to the rapidly changing landscape of precision medicine and digital healthcare. Specifically, the statement addressed the need to increase collaboration and data sharing during clinical trials across industry and academia. Furthermore, the statement described the importance of being able to combine RWD and data from clinical research.

The FDA clearly sees a need to better utilize the technology and data available to clinical researchers. RWD, and the technology associated with how they are shared and utilized, represent a significant piece to the puzzle of solving recruitment and retention issues in clinical trials.

The FDA statement serves as a reinforcement for most sponsors and contract research organizations (CROs) because they are already investing significant resources in methods to modernize clinical trials.{9} Importantly, for the purposes of this article, the investment in, and utilization of, RWD are key focal points for nearly all sponsors and CROs. RWD is beginning to show its value in addressing the issues associated with ineffective clinical trial recruitment and retention.{2,3,9–12)

Sponsors and CROs are seeing the importance of RWD in the design and implementation of their clinical trials. For example, all but one of the 30 organizations surveyed by Lamberti, et al. in 2018 have a RWD department that has been in existence for more than five years, and organizations are beginning to regularly conduct RWD studies to support the development of their clinical trials.{9}

Use with Care

Numerous issues, discussed earlier in this article, drive the lack of adult participation in clinical trials; however, these issues can be mitigated through the utilization of RWD. RWD can address each of the four issues mentioned above (low patient participation in clinical trials, complex protocols, excessive protocol amendments with re-consenting, and bloated sample sizes), provided they are shared and utilized appropriately.

For example, to increase patient participation in clinical trials, RWD can be used to broaden the access to clinical trials. Clinical trials are not always easily accessible to everyone—minority, elderly, low-income, and rural populations often do not have access to clinical trials. However, utilization of RWD in pragmatic clinical trials (PCTs) can allow primary care physicians, using electronic health records, to give clinical trial access to more people.{10}

While PCTs apply to more late-stage studies, randomized controlled trials (RCTs) apply to early- and mid-stage studies. RCTs can also benefit from RWD in the area of patient recruitment. Specifically, RWD can be used to explore inclusion/exclusion criteria for a study under development, and to ensure the criteria are identifying patients. If patients are not identified in the analysis of the RWD, an organization can easily revise the inclusion/exclusion criteria to ensure patients are identified. Thus, once a protocol is implemented, it will be guaranteed that a given patient population exists. In fact, some RWD analysis platforms have a tool for examining the projected number of patients that will likely be identified for a given study.

However, while the above use of RWD addresses subject participation at the level of the study type and protocol design, it does not address other issues with recruitment—namely, complex protocols, excessive protocol amendments, and re-consenting. Utilization of RWD fosters a less complex environment in clinical trials requiring fewer amendments.

Because RWD are actual raw healthcare data, they can be analyzed in a variety of ways—to identify the best way to design a protocol and to ensure protocol amendments are essentially absent from a study (this would also eliminate the need for re-consenting). Of course, protocol amendments and re-consenting would still have to occur if there were unavoidable changes required (e.g., FDA-required changes during the study or updated safety information).

Finally, sample sizes in many clinical trials are excessive. Organizations tend to overestimate the population of subjects needed for statistical significance, and additional subjects often are targeted for the sole purpose of supporting unnecessary endpoints.

Using RWD, organizations can refine their targeted patient population. In fact, RWD can be used to show what the results of a large RCT might be. Specifically, RWD can be used to support a single experimental treatment arm trial. In this example, RWD can be utilized to determine the outcomes of a similar patient population using different treatments already approved for use.{3}

In one of the most significant developments in the use of RWD, a global health research network used RWD to show it could use the available data (and analysis platform) to replicate a large RCT in cardiovascular outcomes for two different diabetes treatments.{12}

The future of recruitment and retention planning in clinical trials will most certainly include the widespread utilization of RWD.

Disclaimer

This article is solely the work of the author and not the author's institution. Accordingly, any of the author's opinions expressed herein are independent of the author's institution.

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Patrick Sturges, MS, CCRP, (patricksturges@gmail.com) is a Clinical Project Leader in the New York City area.

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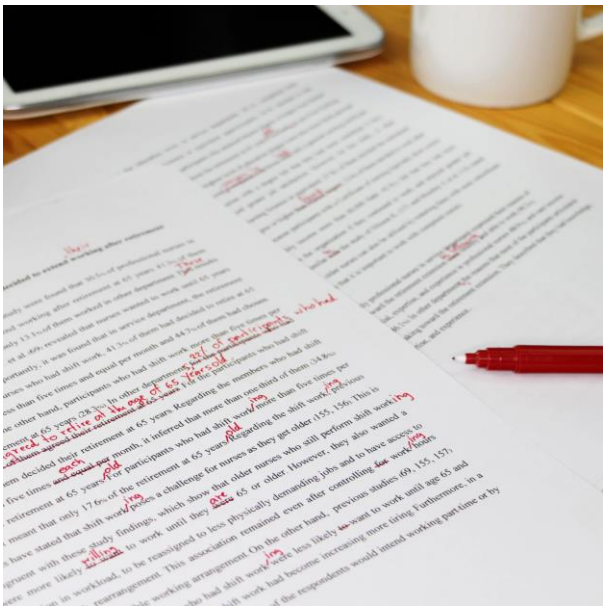
PEER REVIEWED

Developing a Clinical Research Manuscript: From Ideation to Publication and Beyond

Paula Smailes, DNP, RN, MSN, CCRP, CCRC; Christina Nance, PhD, CPI;
Heather Wright, CCRC; Jerry Stein, PhD, ACRP-CP



How do you develop a publishable manuscript? For some, the writing process appears effortless, whether it is producing a highly structured research paper or an opinion piece describing a clinical research process. For others, the barriers often appear to be enormous, especially for individuals who have never previously published. The intent of this article is to discuss best practices for writing and common publishing problems and benefits for authors and the profession.

Publishing an article remains a unique career milestone despite the explosive growth in electronic social media and the many new avenues to communicate information. When an article appears in a recognized journal or publication, the intellectual property it represents is immediately bestowed a higher level of legitimacy. In part, this is due to published articles being distinctly different from unfiltered, unvetted blogs, posts, or e-mails; typically to be published, a serious and thoroughly developed article has been reviewed and approved by a journal's editor and team of reviewers.

While this formal approval process does not guarantee the veracity of the thoughts presented, the process inherently means that someone else, in addition to the author, believes the piece matters. It has undergone some degree of fact-finding and been judged to deserve the attention of readers.

There are, however, many real and perceived barriers that prevent the successful development of manuscripts and their publication. This article will present many helpful practices. It will discuss the etiology of ideas, along with the writing and journal review process. Suggestions will be made for how writing can enhance professionalism and careers via authorship. The system employed by ACRP's *Clinical Researcher* will be used as an example, but most of the information can be generalized to practices used in other publications.

Finding Motivation and Getting Started

When beginning a discussion on the motivation to prepare a manuscript, let's jump ahead to a key question: "What's in it for me?" There are intrinsic, invisible, personal benefits as well as tangible benefits that can positively impact your career (see Figure 1).

Figure 1: The Benefits of Authorship

- Taking the next step forward in career advancement
- Becoming a subject matter expert (SME)
- Self-education made easy
- Networking
- The 95% rule

First, the writing process forces authors to become subject matter experts (SMEs). Knowledge gaps become visible as you move from oral opinion to the written word. Most articles published in peer-reviewed publications and professional society journals are fact-based, often with well-researched citations. When developing these types of manuscripts, authors often need to conduct extensive research and consult with experts to confirm their understanding of facts and processes.

This leads to another quantifiable benefit in terms of professional networking. Expanding your contacts amongst the pool of experts often yields benefits in surprising ways. Invitations to participate in internal company meetings or external speaking opportunities are some common examples. Suddenly, you are the "go-to" person on a specific topic. These consequences can only have positive effects on your career.

The final tangible benefit we want to point out is the "95% rule." In many jobs, it is often the case that the bulk of responsibilities can be performed by 95% of the people who have less training or less experience. Most day-to-day tasks are routine and the response to situations formulaic. When you are a SME, however, you have the opportunity to shine when encountering the rare situation (5% incidence) in which your expertise is needed; preparation is the mother of success.

Beyond personal benefits, authorship is vital to scientific/medical progress and the development of efficient processes. Sharing new evidence and allowing replication is a vital element of proper scientific methodology. Sharing improved processes, interpreting regulatory requirements, and discussing ethical issues helps decrease wasted resources and enhance human rights.

Finding Good Topics

Where do good ideas come from? The sources for potential topics are extensive (see Figure 2 for examples).

Figure 2: Topics to Consider

- Results of/challenges solved during specific clinical trials
- Monitoring and site issues
- Standard operating procedures (SOPs) and quality assurance
- Ethics/human rights challenges
- Audits and regulatory inspections
- Regulatory changes
- Process innovation/efficiency

In some instances, the development of an article naturally flows from the completion of a formal scientific experiment. Writing a manuscript using the standard scientific format (abstract, introduction, methods, results, discussion, conclusion, etc.) required by most scientific/medical journals might be a significant challenge when the required information is not well documented or is scattered amongst a large team. In other instances, the write-up may be fairly easy when based on a grant application, annual report, clinical summary report, investigator's brochure, or biostatistical reports.

Beyond summarizing scientific experiments, manuscripts may often focus on new regulatory requirements, innovative research methodologies, and issues tied to such areas as negotiating research budgets, maintaining a study site's financial health, and improving patient recruitment/retention, staff competencies, or other operational metrics. A significant amount of time is spent by individuals and organizations clarifying confusing regulations and developing processes that improve efficiency. Sharing these insights with others is very valuable to the medical research community.

Finally, potential authors should not ignore the opportunity to convert a previously presented poster or oral presentation into a manuscript. This process essentially lets authors get double mileage for the same effort, and allows authors to incorporate comments received from previous audiences into their manuscripts.

Overcoming Writing Barriers

Let's assume the potential author is well motivated and the core idea for a manuscript well defined. What are the barriers authors typically experience that prevent them from actually writing? Perhaps the number one obstacle is lack of time and urgency. Whether or not a task has long-term importance, some things have to get done as soon as possible; today, right now!

Figure 3: Reasons Writing a Manuscript Gets Delayed

- More urgent tasks (both important and unimportant)
- Fear of failure
- Lack of confidence
- Under-valuing your knowledge, experience, or insight

Developing a manuscript—especially a piece focused on a process innovation—is frequently a non-urgent activity easily pushed aside by the priorities and distractions of day-to-day life. In addition, the rewards for writing are often perceived as subtle, long-term, or non-existent. Delays in writing are inevitable. Other barriers include the fear of failure, lack of self-confidence, and under-valuing one's unique knowledge base or experience (see Figure 3).

Don't Quite Begin at the Beginning

How to begin? If a formal scientific paper is the goal (e.g., describing a well-controlled, double-blind study), it is often best to start with a draft of the methods section. The methods employed and materials used should be well known, making this the easiest section to write. This is often followed by drafts of the results and discussion sections. Last, tackle the introduction and abstract.

Other types of manuscripts should be prepared in a similar manner. First, break the task down into manageable pieces. It is important to recognize that authors are not obligated to prepare drafts in the final order required for the submission or provide complete paragraphs. Start by writing a sentence or two when thoughts develop. Keep a notepad nearby to collect your thoughts at work and at home. Sentences will grow into cohesive paragraphs over time as you write, review, and refine. You may be surprised to find many relevant ideas and reference materials appear in your world once you start writing on a specific topic. It's not magic; it's a new focus.

At the right time, develop a timeline with small, achievable milestones designed to pressure yourself. It may be beneficial to enlist the help of friends, colleagues, SMEs, and editorial advisors and/or staff for the journal you are targeting with your manuscript. Some individuals will decline, but a surprising large number of people will help if only you ask.

Regardless of the type of manuscript or subject being developed, the process is similar. Start writing in small chunks, develop the draft in any order that facilitates the writing process, solicit help when necessary, and revise frequently. Review the paper as a whole to ensure consistency is present, all questions raised get answered, and you have addressed the potential criticisms of the future readers. When you have developed a very good draft, stop writing. After time has passed, re-read the draft with a fresh pair of eyes and begin the revision process once again.

Journal Selection

Journal selection is an important consideration when writing a manuscript. If you need inspiration on a topic, journals often do a "call out" to the public for manuscripts on a particular topic. Some journals often will organize their incoming content (whether solicited or random) around themes assigned to forthcoming issues. If you have an idea, but are not sure how well received it might be, try reaching out to the editor and pitching the idea. The editor may be able to give you feedback on the topic, which may be helpful to you before investing too much time and effort on a topic that, in the end, may only be of interest to you.

A journal's impact factor may also be a consideration. The impact factor is a numerical gauge for the significance a journal has in its field. It also relates to the average number of citations that occur for articles appearing in the journal. If the goal is to get exposure to your manuscript, then choosing a journal with a high impact factor would be a means to do that. However, it should be noted that not all journals track such data.

Further, it's a good idea to consider multiple journals up front, so that if your manuscript is rejected by one, you will already have a Plan B prepared.

Formatting and Other Factors

Other factors related to journal selection and beginning a manuscript are manuscript formatting, length, and style. Preferences for these can typically be found on a journal's website under "Author Guidelines" or similar headings. Current writing styles include those detailed by the American Psychological

Association (APA) in the *APA Publication Manual* (6th edition) and those found in *The Chicago Manual of Style* (15th edition), among many others. The style you follow will dictate how you format such elements as abbreviations, numbers, spacing, headings/subheadings, and reference lists.

There are a variety of referencing software tools available to help writers. Examples include Zotero® and Endnote®, which may have fees associated with their use. If you are using Microsoft Office®, it has a References section built into Word that is free to use (see Figure 4). The References functionality in Word includes a Source Manager option (see Figure 5), which tracks the sources you are using and places them in the style requested by the journal. Should your manuscript not be selected, when you move to Plan B and resubmit to another journal, it may be as easy as a click of a button to reformat content to another style that a different journal requires.

Figure 4: Referencing Software in Microsoft® Word

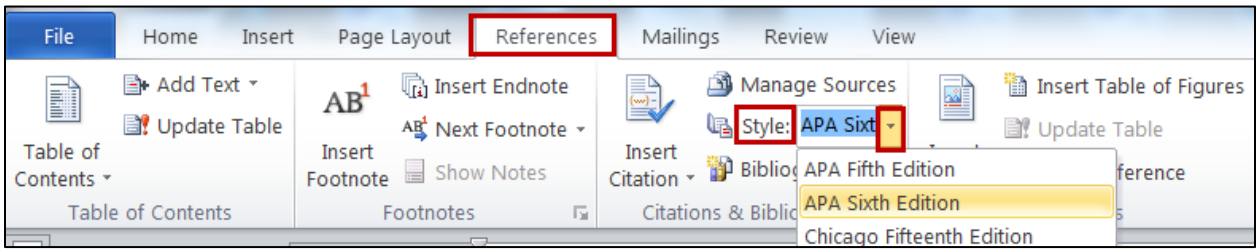
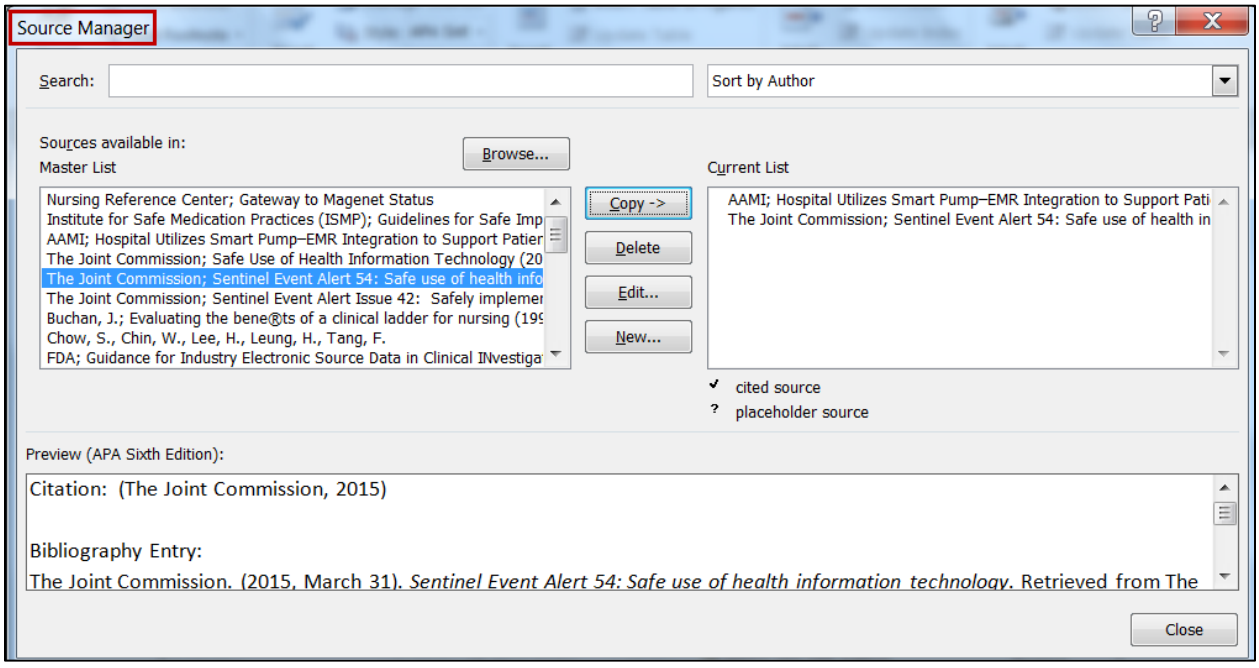


Figure 5: Manage Sources in References of Microsoft® Word



The Peer Review Process

The cornerstone of scientific advancement is peer review. Scientific manuscripts have been subjected to the peer review process prior to publication for more than 300 years. The Royal Societies of Edinburgh and London first began seeking help from their membership with the selection process of articles for their publications in the early to mid-18th century.{1} Scholarly publication is the means by which new work is communicated, and peer review is an important part of this process.

Peer review is a vital part of the quality control mechanism that is used to determine what is published and what is not. When reviewers give a green light to a particular paper, they are saying the scientific findings, concepts, or opinions described in the paper are valid and trustworthy. This is similar to what quality control inspectors do at a manufacturing plant—they check products for imperfections that might cause harm or dissatisfaction in the end-user audience. Inspectors adhere to strict quality standards, discarding any product that doesn't meet the standard. Peer review does the same thing by setting a scientific standard.{2}

The foundation of the peer review process is the editorial advisory board (EAB) of each journal (or whatever name its panel of advisors goes under). The EAB is usually comprised of the journal's editor-in-chief, associate editor(s), and reviewers. Reviewers typically serve in their role voluntarily, whether as members of the association or society publishing the journal, or as *ad hoc* invitees due to their expertise.

Some journals may prefer to use a pool of SMEs that are consulted for reviews in lieu of a formal EAB holding regular meetings and enforcing term limits on the volunteers. Either way, with reviewers helping to verify that the scientific claims being published are valid, consumers can feel a measure of protection against those trying to use "science" to sell their products.

Looking at the value peer review brings to various stakeholders, we see that for authors, peer review provides respectability of their work. For other scientists, peer review acts as a mechanism to help prioritize what they read. For nonscientists, peer review acts like a quality standard that helps make sense of scientific claims.

The peer review process for most journals is initiated by submission of a manuscript by the primary author. If collaborating with multiple authors on a manuscript, it is prudent to define up front who will handle which duties; especially, establish who will serve as the primary author. Once submitted, the manuscript is assessed by the staff editor(s). If the manuscript is determined to meet at least the minimal requirements for bolstering the mission of the journal, EAB reviewers are invited to review it. Depending

on the complexity of the topic and the journal's practices, there will usually be at least two reviewers tasked with evaluating the manuscript. Ideally, to minimize potential biases in both directions, the journal editor(s) will prevent the author(s) from knowing who the reviewers are, and the reviewers from knowing the identity of the author(s).

When you submit your manuscript, you should be given some idea as to how long it takes to get through peer review. Reviewers may need a few weeks to a few months to review a manuscript—potentially through multiple revisions—so it's important to know what to expect as you wait.

Reviewing the Manuscript Anatomy

The peer review process assesses multiple aspects of the manuscript by breaking it down into its components. Typical points reviewers consider when assessing the content include:

1) Title: Does it accurately reflect the manuscript's content?

2) Abstract: Does it correctly summarize the salient points made in the manuscript?

3) Introduction: Does it provide adequate background and rationale for the topic?

4) Body: In the case of a study involving human subjects, are the patient sample, procedures, and data analysis described clearly and in sufficient detail? If applicable, was the study approved by an institutional review board and conducted with accurate and appropriate statistical analysis?

5) Discussion/Conclusion: Is it consistent with the manuscript's contents? Can any results obtained from a patient sample be generalized to the population?

Guidelines provided to reviewers typically direct them to pay attention to a variety of factors of importance to a well-written manuscript. Some of these are:

1) Is the subject matter important, timely, and relevant?

2) Is the quality of writing clear, straightforward, easy to follow, and logical?

3) If tables and figures are used, are they well presented?

4) Is the study design appropriate, rigorous, and comprehensive?

5) If the manuscript involves findings from a study in human subjects, does the sample adequately represent the targeted population and have sufficient size for quantitative research?

6) Is the literature review thoughtful, focused, and up to date?

On the opposing side of the spectrum, there are some common pitfalls of a poorly written manuscript which should be avoided. These include a disorganized presentation; difficult-to-follow phrasing and terminology; citations not present and/or evidence of plagiarism; research summarized without appropriate statistics or description of the study populations; instruments that are inappropriate, incomplete, or insufficient; and results/conclusions being over-interpreted.

Outcomes of Peer Review

After a thorough reading of the manuscript, the journal reviewers submit their recommendations independently, and this input is typically aggregated by the editor(s) and passed on to the author(s). The overall recommendation at this stage will be either full acceptance (no changes necessary beyond editing to fit the journal's style), conditional acceptance with revisions requested (either minor or major), or rejection of the manuscript.

Reject

So let's start with the outcome that you didn't want. You're told that the manuscript is rejected, as either inappropriate for the journal, too similar to other manuscripts already published in the journal, or so poorly developed that the reviewers and editors are not willing to give it a second chance. While it's perfectly natural to be sad, it's OK; as mentioned before, having more than one journal in mind will help soften the blow. Using Plan B, a citation manager will have your manuscript reformatted quickly. While you may not like the feedback you received, incorporating those suggestions may make your submission stronger the next time. After you make any changes and before submitting to another journal, make sure you have a colleague review the manuscript once again, to provide feedback for you, too.

Revise

The next possibility is that your paper is accepted pending revisions requested by the peer reviewers. The revisions may be considered minor or major. If you agree with the revisions, submit a reply to each reviewer comment and resubmit the manuscript in tracked changes format. Remember that just because a reviewer wants changes does not mean you have to provide them. If you disagree, you can defend what

you wrote. Sometimes reviewers can misunderstand the content or wish you to go down a road with your topic that you didn't intend. Always be kind and considerate when you respond to comments, and remember that the reviewers are volunteers. You also have the option of declining to revise the manuscript and submitting it to another journal; however, you should never submit a manuscript to multiple journals simultaneously.

Accept

The last possibility is your desired outcome, and that is the manuscript is accepted (with or without a round or two of revisions). When that happens, you get to celebrate! You then move into the final steps toward publication. The first steps for most journals is to secure from you a transfer of copyright giving the journal permission to publish your manuscript. Next will be the editing process. Once edited, the updated text will be sent to the author for review. It's appropriate at this time to disagree with how it was edited, and you can continue to work with the journal until everyone is in agreement on how the text reads and how any tables/figures/artwork are presented. This should be verified through a "final proof" of the article being sent to you before it goes to print and/or online publication.

Post-Publication Considerations

So now you are published! Congratulations! If the journal has a print version, you can ask for extra copies of the issue including your article. Don't forget to add this accomplishment to your CV and make sure you include any authors with whom you collaborated. You should consider sending copies to SMEs who you have cited and individuals with similar interests. Always share your success, especially with your bosses during job evaluations, to show that you go above and beyond what is being asked of you professionally. LinkedIn, Facebook, and ResearchGate are also great tools to use when sharing your publication.

One consideration is that you can't publish the same manuscript twice. Also remember that once you have your manuscript published, if you write again on a similar topic and base some of the content on your earlier publication, you need to cite it. Chances are once you get the first manuscript done, you will be more receptive to developing a second, third, and fourth.

Improving Your Writing Skills

There is always room for improvement with writing for even the most experienced writer. You might consider taking a writing class, which can be helpful if you are not confident with how to structure a

paper or use citation tools. You can also find tutorials online; for instance, YouTube can provide help on citation managers, writing basics, and other areas.

Belonging to professional organizations and reading their publications actually helps your writing. Articles are usually constructed the same way over and over with an abstract, introduction, body, and conclusion. The more you read professional journals, the more this helps you with your own writing. Lastly, there is an American Medical Writers Association journal, which can also provide helpful tips for your writing efforts.

Another means of improving your writing is to join a start a journal club. These are popular in academia, but certainly not limited to these institutions. Discussing articles and research studies can enhance your professional practice.

If you need help with referencing and citations, Purdue Owl is an online resource to help you with your formatting. Seeking advice from others is another avenue. Sometimes it can be hard to ask to for help, but you would be surprised at the number of people who would be willing to help you. This is especially true when approaching experienced colleagues or those in leadership positions who have a lot of experience writing. Finding a mentor can be very beneficial throughout this process.

Conclusion

Writing for publication can be challenging, but knowing how to begin, what to expect, and how to plan for success can make it much less intimidating. The key component of professional writing is the peer review process, which is designed to validate the evidence that is placed into print. Peer review can help make manuscripts stronger by offering input and evaluating manuscript integrity. Writing leads to professional growth and, with time, a novice writer can ultimately become an SME and leader in his or her field.

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Note: The four authors speak from a strong experience base. We have read, critiqued, accepted, and rejected hundreds of manuscripts as editorial advisors for the Association of Clinical Research Professionals and other organizations. We have also successfully published hundreds of our own articles in peer-reviewed journals and other publications over the last 40 years. Our goal is to help others—to pay it forward.

Paula Smailes, DNP, RN, MSN, CCRP, CCRC, (Paula.Smailes@osumc.edu) is a Visiting Professor at Chamberlain College of Nursing and Senior Systems Consultant at The Ohio State University Wexner Medical Center.

Christina Nance, PhD, CPI, (cnance@bcm.edu) is an Assistant Professor in Pediatrics, Pathology & Immunology, Tropical Medicine, and Epidemiology & Human Genetics at the Baylor College of Medicine, Texas Children's Hospital, and University of Texas in Houston.

Heather Wright, CCRC, (heatheraspenwright@gmail.com) is an accomplished clinical research professional in the Tampa Bay area of Florida.

Jerry Stein, PhD, ACRP-CP, (summercreekc@gmail.com) is President and Owner of Summer Creek Consulting, LLC in Fort Worth, Texas.

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HOME STUDY

Connecting the Research Community

Utilization of Real-World Data to Enhance Recruitment and Retention of Clinical Research Participants

LEARNING OBJECTIVE

After reading this article, the participant will be able to describes types of real-world data and how they may be applied within the context of clinical trials.

DISCLOSURE

Patrick Sturges, MS, CCRP: *Nothing to disclose*

1. Streamlined real-world data (RWD) offer which of the following advantages for planning for participant recruitment and retention?

1. Optimized patient participation
2. Enhanced adherence to enrollment windows
3. Flexible inclusion/exclusion criteria
4. Close attention to budget parameters

A. 1, 2, and 3 only
B. 1, 2, and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only

2. What is a primary cause of patient recruitment/enrollment accounting for up to 40% of a clinical trial's budget?

A. Frequent extension of recruitment/enrollment windows
B. Patients enrolled from greater distances generate greater expenses
C. Principal investigators luring in more patients with large incentives
D. Sponsors fining study sites for failure to meet enrollment targets

3. Which of the following is cited as an example of a source of RWD?

A. Online dating sites
B. Legal settlements
C. Business plans
D. Insurance claims

4. Which of the following are cited as factors in the effectiveness of recruitment and retention for clinical trials?

1. Potential participants who are left unrecruited
2. Companies with competing products discourage trial volunteers
3. Study sites do not offer enough money to subjects
4. Large sample size compared to study population

A. 1 and 2 only
B. 1 and 4 only
C. 2 and 3 only
D. 3 and 4 only

5. Which of the following is mentioned as a method being explored for optimizing recruitment and retention of trial participants?

A. Mandating participation for the uninsured
B. Making all trials government-funded
C. Enhancing patient engagement
D. Eliminating legal barriers in large states

6. Findings from a survey by Lamberti, et al. include which of the following points?

A. RWD studies are becoming more common in support of clinical trials.
B. RWD studies are popular but considered too expensive by most sponsors.
C. RWD studies are seen as poor substitutes for direct surveys of patients.
D. RWD studies are becoming less common as risk-based monitoring increases.

7. Using RWD in pragmatic trials allows physicians to do which of the following?

A. Reduce travel-related costs to more patients.
B. Increase drug dosages to more patients.
C. Make informed consent less confusing for patients.
D. Make trials accessible to more patients.

8. What does the author say RWD can be used to explore in the context of randomized controlled trials?

A. Suspected noncompliance
B. Inclusion/exclusion criteria
C. Serious adverse events
D. Placebo responses

9. According to the author, unnecessarily large sample sizes in many trials are related to which of the following?

A. Unnecessary protocol amendments
B. Unnecessary risk/benefit analyses
C. Unnecessary endpoints
D. Unnecessary drop-out rates

10. How can RWD be used to support a single-arm trial?

A. By showing results in similar patients who used already-approved treatments.
B. By showing results in similar patients who used the treatment in off-label situations.
C. By showing results in similar patients who failed to follow the trial instructions.
D. By showing results in similar patients who had compassionate use waivers.

Developing a Clinical Research Manuscript: From Ideation to Publication and Beyond

LEARNING OBJECTIVE

After reading this article, the participant should be able to describe the steps in developing a clinical research manuscript, the importance of and possible outcomes from peer review, the elements of a manuscript's anatomy, and steps to take post-publication.

DISCLOSURE

Paula Smailes, DNP, RN, MSN, CCRP, CCRC; Christina Nance, PhD, CPI; Heather Wright, CCRC; Jerry Stein, PhD, ACRP-CP: *Nothing to disclose*

11. According to the authors, serious published articles are different from informal ones in which way?

A. Serious articles are published only upon promise of payment from a journal.
B. Serious articles are written only by teams of authors with advanced degrees.
C. Serious articles are reviewed and approved by an editor and reviewers.
D. Serious articles are submitted to multiple publications at the same time.

12. The authors cite which of the following as benefits of authorship of scholarly articles?

1. Journal discounts
2. Self-education
3. Networking
4. Career advancement

A. 1, 2, and 3 only
B. 1, 2, and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only

13. The authors cite which of the following as a vital element of proper scientific methodology?

A. Sharing opinions and study results with competitors.
B. Sharing new evidence and allowing replication.
C. Sharing intellectual property with potential investors.
D. Sharing authorship credit with student advisees.

14. Which of the following is cited as a source for possible article development?

A. Previously presented posters or oral presentations.
B. Manuscripts by other authors with lapsed copyrights.
C. Opinions about studies outside the author's expertise.
D. Data from studies that fell short of statistical significance.

15. What is a good way to start developing a formal scientific paper?

A. With criticism of previous researchers' work.
B. With acknowledgments of all funding sources.
C. With a draft of the methods section.
D. With a statement of informed consent.

16. What does a journal's impact factor do?

A. Serve as a gauge for the journal's circulation.
B. Serve as a gauge for the journal's significance.
C. Serve as a gauge for the journal's reviewers.
D. Serve as a gauge for the journal's longevity.

17. Peer review is described as similar to what activity at a manufacturing plant?

A. Quality control
B. Routine maintenance
C. Ethics committee
D. Budget analysis

18. How can bias concerning a reviewed manuscript best be controlled?

A. Both the author(s) and reviewers know each other's identities.
B. The author(s) know the reviewers' identities, but not the other way around.
C. The reviewers know the author(s)' identities, but not the other way around.
D. Neither the author(s) nor reviewers know each other's identities.

19. Which of the following are cited as examples of pitfalls of a poorly written manuscript?

1. Inappropriate fonts and spacing
2. Over-interpreted results/conclusions
3. Disorganized presentation
4. Written in a foreign language

A. 1 and 2 only
B. 1 and 4 only
C. 2 and 3 only
D. 3 and 4 only

20. What happens when a reviewer requests that revisions be made to a manuscript?

A. The author should withdraw the manuscript from review.
B. The author is obligated to make all requested changes.
C. The author is not obligated to make changes.
D. The author should perform a total rewrite.