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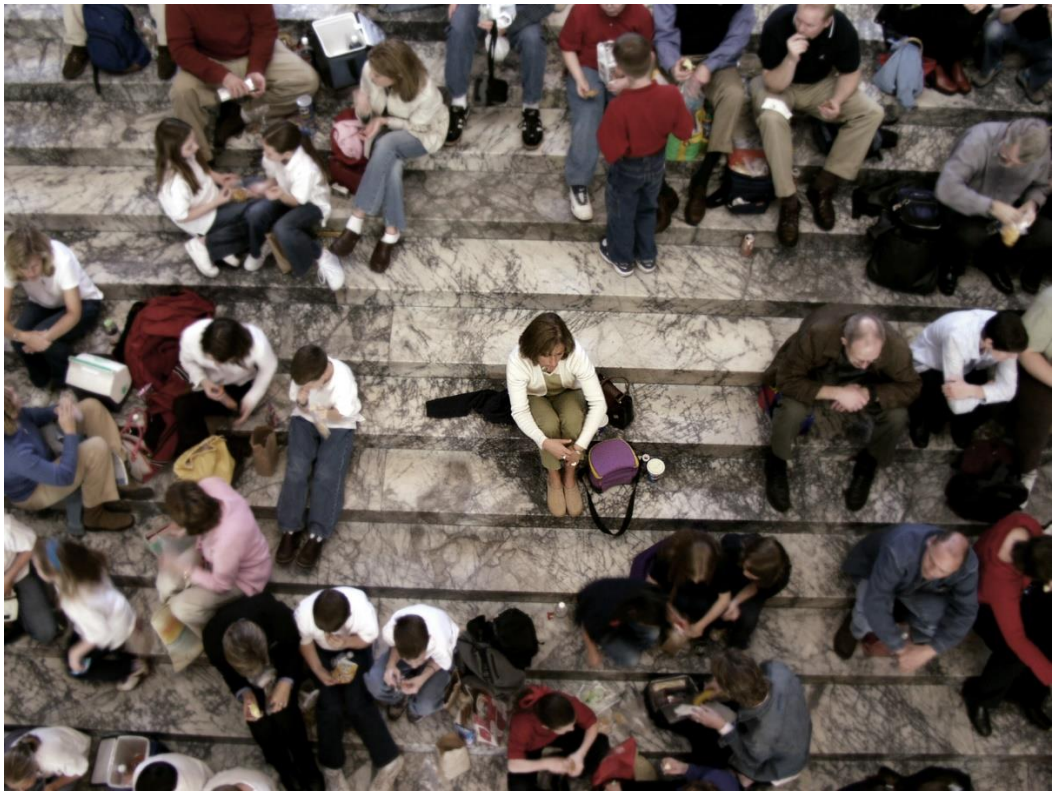
Clinical Researcher™

The Authority in Ethical, Responsible Clinical Research

August 2019 (Volume 33, Issue 7)



Connecting the Research Community

Clinical Researcher™

Association of Clinical Research Professionals

Clinical Researcher—August 2019 (Volume 33, Issue 7)

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Clinical Researcher—August 2019 (Volume 33, Issue 7)

EXECUTIVE DIRECTOR'S MESSAGE

Getting the Future We Deserve

Jim Kremidas

From the Philip K. Dick novel-turned-miniseries *The Man in the High Castle* to Philip Roth's novel (and soon-to-be miniseries) *The Plot Against America,* alternate history in science fiction and fantasy can be thought-provoking as it contrasts our real world against an artist's "what if" conception of how a change in the way things went in the past might lead to a different reality for our lives today. Fictional though they be, if skillfully presented, these alternate worlds can remind us of what we've gained or lost by how our own reality has played out so far.

Whether it's in the pages of *11/22/63* by fright master Stephen King or in a more family-friendly film like Frank Capra's *It's a Wonderful Life*, alternate history scenarios often focus on something *not* happening (e.g., President John F. Kennedy isn't assassinated or George Bailey is never born) or different outcomes of important events (e.g., Germany and Japan winning World War II, as depicted in *High Castle*, or Franklin D. Roosevelt losing his presidential re-election bid to Charles Lindbergh in 1940, as explored in Roth's book).

There are a few possible reasons I've had alternate history on my mind recently. I've had the opportunity to do a lot of traveling in the past few months to represent ACRP at various industry functions. Sometimes I'm a speaker and other times I'm an attendee learning from thought leaders with unique perspectives and accomplishments.

Maybe it's the chance to daydream on that airplane to Chicago or the Acela to Philadelphia, but of late I've been thinking about an alternate history for the clinical trial workforce. And like the best science fiction, what just a few years ago seemed out of reach or even outlandish is beginning to look quite possible.

In my alternate history daydreams, the clinical trial workforce is well trained, with clear career paths and certifications grounded in meaningful skills and core competencies. The benefits are obvious. Turnover declines. Burnout recedes. Drugs are approved more efficiently and safely. Patients live longer, better lives.

Watching and reading alternate history stories can be entertaining, angering, and frustrating, particularly when they get dystopian. But they also remind us that we can control much of our own destiny when it comes to many aspects of our own lives. We can demand—and manufacture—a better kind of future.

For example, last month your association and the Society for Clinical Research Sites (SCRS) announced a new partnership to offer SCRS clinical research site members complimentary Good Clinical Practice and ethics training. Under the partnership, SCRS member organizations and their clinical research teams will have immediate access to two of ACRP's industry-leading online, on-demand training programs at no cost:

- Introduction to Good Clinical Practice (GCP)
- Ethics and Human Subject Protection: A Comprehensive Introduction

It's just one of the many projects we've undertaken in 2019. Another is our new partnership with the Alliance for Clinical Research Excellence and Safety (ACRES) as it rolls out its program to accredit clinical research sites worldwide. There will be lots more to share in the coming months.

Let's keep working hard together to advance the professionalization of the clinical trial workforce. Let's keep building new certifications and training modules. In this manner, a highly skilled and well-trained clinical trial workforce is moving quickly from the wish list to reality, and I want to thank you for all you've done to help in this important work.

As always, feel free to reach out to me with your thoughts and concerns about the exciting future of clinical research that we will all get to share.

Jim Kremidas (jkremidas@acrpnet.org) is Executive Director for ACRP.

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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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PEER REVIEWED

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

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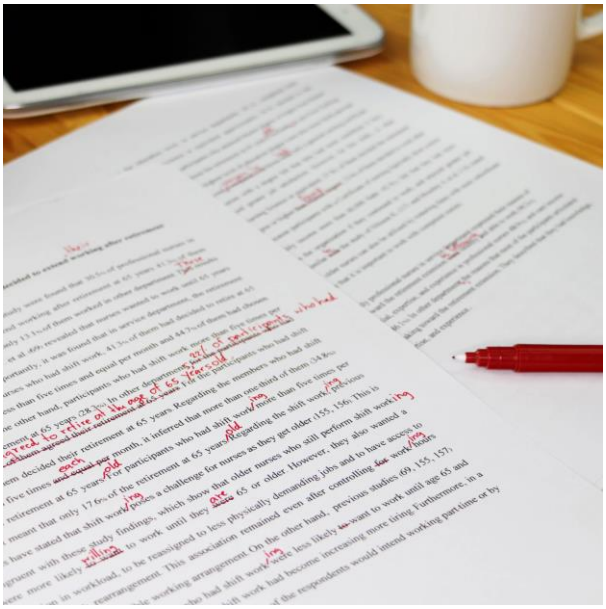
Heather Wright, CCRC; Jerry Stein, PhD, ACRP-CP



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

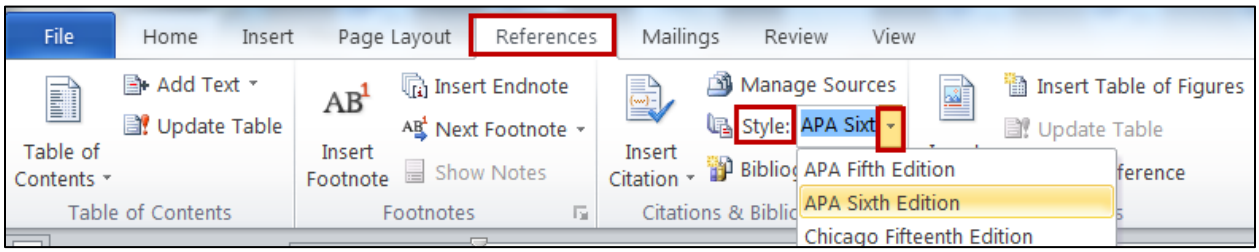
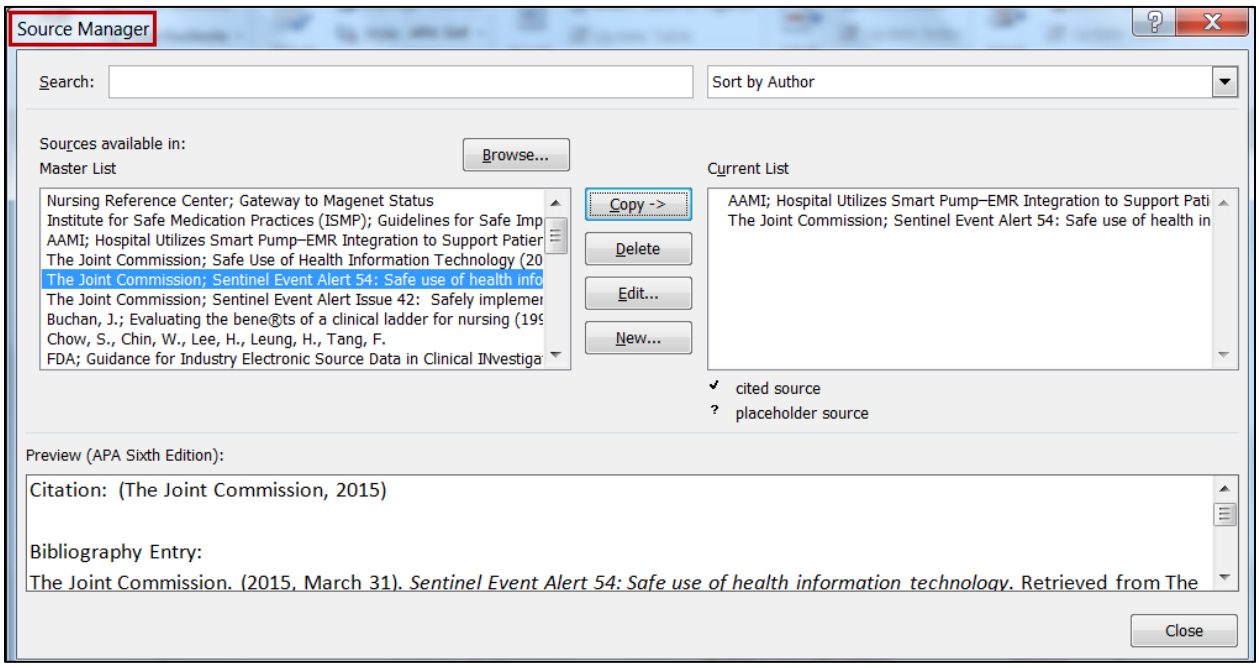


Figure 5: Manage Sources in References of Microsoft® Word



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.

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DATA-TECH CONNECT

How Humanized Machine Learning is Giving the Life Sciences Industry a Shot in the Arm

David Bennett

The life sciences industry currently finds itself facing a perfect storm of challenges—from society's rising concern over health costs to changes in the physician's role. Artificial intelligence (AI) and machine learning are being rapidly adopted to transform existing business processes and unlock additional value and insights, but the required data science talent is in desperately short supply. The next generation of accessible machine learning platforms will be crucial in helping departments working from the research and development (R&D) stages through to product commercialization to unlock the full value of their data.

Deloitte research from 2018 shows that productivity and R&D returns in biopharmaceutical companies have dropped to their lowest levels in nine years. The conundrum for these companies is where the R&D burden should fall, and they are continually evaluating whether to move efforts in-house, outsource to smaller companies, or involve academia in the process with a view to pursuing automation.

All this comes at a time of an emerging and shifting dynamic of rising payer—or formulary—power while physicians' prescribing influence decreases and the cost of cutting-edge healthcare begins to exceed society's willingness to pay.

Meanwhile, larger, more agile, and tech-focused companies such as Google and Amazon are sizing up the life sciences space with an eye to discontinuous disruption of the established order. These disruptors bring extensive financial clout and proven expertise with emerging technologies

as a key enabler and differentiator, but technology also holds the key to the ability of "traditional" life sciences companies to fight back.

Machine Learning to the Rescue

How can the life sciences sector as a whole boost productivity, reduce the time to market, and unlock the full value of its data? The answer lies in the ability to successfully internalize and operationalize the promise of AI and machine learning, and to move it beyond the current ivory towers of data science.

Released this year, the *22nd Annual Global CEO Survey* from PwC on healthcare and pharmaceutical trends revealed the stark contrast between data abundance and quality. C-level executives are hungry for data on brand and reputation, financial forecasts, and customer demands, but they simply do not have access to data that are fit for purpose or tools that are capable of deriving comprehensive business insights from the data that they do have. This is at a moment when the industry generates more data than ever before.

New developments in applied machine learning offer the opportunity to quickly explore data and identify complex patterns from vast datasets, including on patient health measurements, clinical trial feedback, and research outcomes.

Solving AI Pain Points for the Industry

Pharma businesses are already seeing return on investment from initial projects. In the United Kingdom, the Medicines Catapult *2019 State of the Discovery Nation* report revealed that 90% of small and medium enterprises (SMEs) in the pharma industry required data science as part of their drug discovery operations, with half of these SMEs requiring AI and machine learning. However, there are still issues associated with AI in the life sciences industry.

Capabilities for data discovery are not clear and curation and preparation are still limited—all significantly lengthening the average project timeframe. There are also transparency considerations. Is the selected machine learning model reproducible across other datasets and

business problems? Is the prediction accuracy visible, and can output easily be understood without ongoing reference to specialist data scientists?

Many of these pain points will be resolved by turning to platforms that automate significant amounts of the data preparation process, that are truly end-to-end and transparent in their operations, and that ensure the user is kept fully in the loop.

Humanized Machine Learning Empowers the Citizen Data Scientist

With talented data scientists in scarce supply, the skills gap is continuing to pose challenges to life sciences organizations. Existing data science departments do not have a wealth of data scientists, so their talents—and workloads—are reserved solely for the most business-critical and time-sensitive tasks, particularly in the R&D space. This means that other business units (e.g., medical, commercial) enjoying an equally vast although different wealth of data are unable to harness this expertise to generate insights and refine their operations with any velocity.

New applied machine learning technologies enable these life sciences organizations to bring machine learning and other advanced technology within the remit of employees of all skill levels, helping these problem owners become “citizen data scientists” in their own right. The ideal platforms for such technologies put the ability to prepare, manipulate, and visualize data for creating, managing, and optimizing deployable machine learning models within minutes into the hands of every employee, effectively coaching the user from data preparations right through to model deployment and management.

Such platforms are designed with accessibility in mind, eliminating the need for extensive training or a background in data science. A business or science problem owner can quickly harness the full power of advanced machine learning, intuitively augmenting his or her existing expertise and problem knowledge.

The bottlenecks of a limited data scientist talent pool are avoided, and projects can be completed quickly—without adding weeks or even months to the timeframe of a project that is waiting to be resourced.

Far-Reaching Applications Unlock Business Value Across the Enterprise

Beyond all the promises that have been made for AI in drug discovery, the real transformation in productivity in life science companies value chain will be wrought by augmenting the existing workforce with AI and moving beyond the realm of the specialist data scientist. Machine learning can be harnessed to find and enroll patients in the most suitable trials and facilitate the entire patient journey. Market access, sales, and marketing teams can make better decisions faster, their productivity while using scarce resources such as medical science liaisons can be transformed, and patient-centric, real-world evidence can be made truly useful.

Transforming Every Step of the Life Sciences Value Chain

While we already talk about the applications of AI and machine learning in life sciences, the next generation of cloud-based solutions is now poised to bring these advanced capabilities into the hands of every department and employee with a dataset and the desire to extract greater business insights and value.

These solutions can be easily deployed to rapidly tackle specific business problems, empowering pharmaceutical companies and other players in the life sciences sector to unlock the full value of their data.

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ETHICS IN ACTION

Research Bioethics Emphasis Goes Worldwide Through International Fellows Program

This interview with Subhashini Gopal, MSc, MPhil, a psychologist and coordinator of psychological services at the Schizophrenia Research Foundation (SCARF) in Chennai, India, focuses on her experiences as a participant in the WIRB-Copernicus Group (WCG) Spring 2019 International Fellows Program. Founded in 2002, the program helps train global healthcare professionals who want to establish the infrastructure of ethical oversight of research in their countries. It features ethics and regulatory training at WIRB in Puyallup, Wash., and at the Division of Medical Ethics within the Department of Population Health at the Medical School for NYU Langone Health. Gopal is currently pursuing a PhD in psychology.

Q: How would you describe SCARF and your role there?

A: SCARF provides critical care for patients with mental illness and serves as a research foundation. When the organization was founded, it focused on patients with schizophrenia, but it has since expanded to include patients with all kinds of mental illness. SCARF has 150 to 170 staff members across a main center for outpatient care and three residential centers. I am involved in both clinical care and research at SCARF.

Q: Why did you join the WCG International Fellows Program?

A: In April 2018, I took over the role of Member Secretary for the SCARF Independent Ethics Committee (IEC). Bioethics was a new area for me, even though I am a researcher and get involved in a lot of research projects at my organization, so I wanted to learn a lot more about it.

Research ethics are especially complex in our field because we deal with the most vulnerable patient populations—those who have compromised autonomy and who are not able to decide what is in their best interest. I wanted to know how these vulnerable patient populations should be approached from an ethics perspective, and to learn from the experiences of healthcare professionals working in other developing countries.

Prior to joining the program, I thought that every country would have basic guidance or ethical principles that researchers had to follow, but I learned that India is advanced in that regard. Some countries have no guidelines laid out for them at all, and that shocked me.

Q: Which organizations provide ethical guidance in India?

A: The Indian Council of Medical Research has developed some guidelines. Researchers also have to apply to the Drug Council General India to obtain approval to conduct clinical trials. However, there is no central regulatory body overseeing the trials.

Q: What part of your work are you most proud of?

A: I am really proud of the patient care that I am able to provide, and the interventions I deliver that bring significant improvements to an individual's quality of life.

My work is rewarding, but it is also very challenging. There are a lot of crises involved with mental illness. We can see patients doing really well one day, but the next day they can come with a full-blown relapse of their illness. If I'm able to bring a change in one person's life, if I can make an effort that is reaching them, then I feel satisfied and proud about it.

Q: Is an IEC in India set up differently from an institutional review board (IRB) in the U.S.?

A: The composition of both groups is similar and they both review research protocols, but our IEC is focused on SCARF, so it only reviews mental health research. Furthermore, we need to have someone serving on our IEC who has a family member with a mental illness; they can represent the patient's perspective because they see what challenges a patient with mental illness faces on a daily basis.

Our IEC meets every three months to review research protocols developed by our researchers and graduate medical students on site. In contrast to what we do, the review process at U.S. IRBs is very structured—they have very strict standards and checklists. That's not the case in India.

Q: What are the most valuable skills or ideas that you've learned from the Fellows program?

A: Starting from the basic elements, we learned the history of ethics and how ethical principles have evolved. Then we heard about the U.S. Food and Drug Administration regulations and the categories of research, and how transferring them to a different culture is a big process. They cannot just be repeated in a local population or culture. What I learned will help us to shape our own evolution.

Q: What cultural differences will impact how you put these concepts into effect?

A: In India, we will do an intervention; we will go into the community and into the villages to recruit participants for a research program. It's not easy. Their education and their level of comprehension are completely different. Making them informed, so that they can consent to the research, is a bigger challenge for the researchers in India than it is for those in the U.S.

We work with community leaders and explain to them the consent process, but the problem lies in getting participants to sign an informed consent. There are people in the villages who may have been cheated because someone got them to sign a paper and their property was taken. To get them to sign an informed consent is not that easy.

Others view researchers as doctors, and they equate doctors with god, because they are saving their life. So, when a doctor goes into the community to do research and get an informed consent,

even though the doctor sits down and takes time to explain the intent of the research, they blindly love or hate it.

Even in defining risk, there is a contextual difference. To someone who has a city life, risk might be different.

If someone in a city got a fever, they might not go to work the next day. Someone with different living conditions and socioeconomic status might still have to go to work. They won't take any kind of physical health or emotional problem as seriously as the person in the city.

Q: What experiences from the Fellows program would you like to implement in India?

A: I would like to propose some changes to our standard operating procedures. WIRB has a large checklist, which makes the work easier. I also plan to hold a workshop on how to write an informed consent form, so that we can create a more uniform process in our organization. It is something that I can bring to the researchers in my region.

It is a researcher's responsibility to behave responsibly with his or her research subjects. The researcher has to make a point to be ethical, to be disciplined, and to follow the standards to protect those who volunteer to participate in studies.

This Q&A was developed for WCG by Rana Healthcare Solutions.

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SCIENCE & SOCIETY

Bringing Results to Patients: A Way Forward Using Collaboration, Integration, and Datasharing

Al O. Pacino

To benefit the clinical research experience, global connectedness across technological capabilities and industry-focused leaders will be key to generating clinical discovery.

When thinking about the direction of technological innovation in the modern clinical research enterprise, we are faced with tracking the inputs of every stakeholder imaginable. Companies are sprouting up all over the globe to fulfill the very specific requirements of what are often narrow segments of the current medical research and development market. Examples include the providers of technology and services for clinical trial management systems (CTMS), trial master files, patient recruitment, contract research organizations, and more.

While many of these companies and organizations are offering unique opportunities for the future of clinical research, some are asking along the way, “How can we ensure these innovations are able to bring results to patients?” We must think about modernizing the culture and incentivizing the establishment of goods and services that will truly make life better for those who need them most.

From the viewpoint of an investigative site, the way to ensure that this question is adequately answered is to first consider whether professionals and patients will be directly impacted by the innovation in a cost-effective and efficient manner. Second, will there be measurable benefits brought to patients, staff, and administrators?

The View from All Sides

Technologies are supposed to assist investigative sites for the purposes of ensuring clinical research readiness and economic and professional prosperity. A site strategy should include the implementation of mechanisms which will enhance the educational opportunities, market visibility, and quality of life for patients as well as clinical practitioners.

In order to positively impact the future of clinical research, entrepreneurs should approach the system as a whole:

- By implementing centralized common directories, organizations can share their research with the global market while still maintaining complete control over their studies. Implementation of local, single-point access common directories and common applications though distributed systems for local healthcare professionals and employers can become a reality. Including apps that target the fostering of compliance-based competencies for staff, better methods of patient identification, and other important study-fulfillment goals can benefit both staff and local patient populations. The right technological infrastructure to enable capacity building should also be able to ensure the quality of research by monitoring study involvement and decreasing the amount of time the study takes to completion. The overall vision is to elevate the chances of connectivity for the purpose of bringing the right solutions to the right institutions.
- In an industry where lives are at stake, it is critical that the latest and greatest information is easily accessible. Through the kind of connectivity described above, this information is shared and distributed throughout a growing network of healthcare professionals. Bringing the best products, services, specialties, technologies, and education to bear on globally standardized healthcare will save time, money, and lives. The key to integrating a successful plan at any investigative site or site network is to eliminate redundancy and reduce time of care to patients.
- Why teach a few people at a time, when you can educate millions around the globe? Building a greater capacity for delivering certification programs to document competencies globally will improve staff proficiency and patient safety, promote inter-rater reliability, and protect the privacy, ownership, and distribution of professional and

business information. By creating online training modules that are easily accessible, educators can be allowed to retain control over their product while increasing access to their teachings and promoting standardization of skillsets.

- By reducing and ultimately eliminating the cost of distributing educational standards, clinical participation is increased. Creating authorized distribution channels to provide a real-time connectivity between consumers and providers is paramount to healthcare and clinical research professionals who need to focus on providing proper care to their patients. The need for ensuring that diverse patient populations are participating in clinical research is ongoing and increasing. Managing the cost of educational requirements improves competencies and the overall levels of clinical research quality and data integrity.

Conclusion

Connective, centralized, common, and sustainable systems are going to be essential for offering clinical research as a standard of care. Standardization is the key to optimizing patient populations and the economic potential for investigative sites around the world. We live in an age where many services are "on-demand," readily accessible through shared directories, and viewable through multiple systems, including smart phones. If we tailor our approach to clinical research with the idea that clinical discovery can be done faster with the technology we currently have at our fingertips, we will be able to enhance the quality of life for many.

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CRA PATHWAY

Don’t Judge a Site by its Cover

Elizabeth Weeks-Rowe, LVN, CCRA

As children growing up, we are taught to never judge a book by its cover, but to look within for the true character of a person. As researchers, we are taught to gather and analyze data before forming our ultimate hypotheses. This sage guidance is integral to site and investigator evaluation/selection, and should be included in every clinical research associate (CRA) training curriculum on the topic.

Don’t judge a site by its “cover.” Don’t let a superficial first impression influence your final opinion of site selection. Conduct a comprehensive evaluation visit that considers all site elements beyond brick/mortar and site location. This will ensure a fair, accurate process.

The Eye of the Beholder

There is no perfect site and any pursuit (of such) is fruitless. There is, however, an abundance of good sites possibly overlooked due to unfortunate factors of geography, physical presentation, and other details—for all the wrong reasons.

A site may not be in the best neighborhood or the most attractive building. Perhaps the area leases are priced unreasonably, and they must opt for what is affordable for the opportunity to conduct clinical trials. Sparkling equipment and architectural design do not guarantee credible research, but could disguise quality issues. The outer appearance does not speak to competencies of the staff within.

Even world-renowned health organizations, with presumed excellence, may rest on laurels long undeserved. Your most successful site may be in an inconsequential strip mall, in a semi-run-down neighborhood, and overlooked because the researcher neglected to take a second look.

Measure Twice, Strike Once

Several years ago, a remarkable site director reminded me of the importance of confirming the true character of a site before making the final selection recommendation.

I was tasked to evaluate a research site in the Southeast. The scheduling and visit confirmation had been a seamless process of responsive communication with an enthusiastic site director. I was looking forward to a productive visit with an experienced investigational site.

As I arrived at the site, I took note of the location. An ordinary strip mall, in a less-than-desirable neighborhood, flanked by a medical equipment retailer and an empty leasing office. Hardly a burgeoning medical center, but I banished any misgivings and entered the lobby. The initial presentation could mean nothing, or speak volumes, and it was my task to make that determination at the end of the evaluation.

The lobby was sparsely decorated, but extremely clean; sparking linoleum floor, not a speck of dirt in site. A cheerful receptionist announced my presence as I checked e-mail and waited for the site director to appear. Moments later, a professional-looking gentleman entered the lobby and extended his hand in greeting. He thanked for coming to their site as he escorted me past several rooms to his office in the back of the clinic.

The director explained that he shared space with the site's sub-investigator, a family practice physician, and though it was a small space, they certainly utilized it efficiently. The director's office stored regulatory binders and lab kits on separately labeled shelves. A small floor filing cabinet held documentation on all of the current employees' training certifications, which he presented for my review.

Two small rooms comprised the site's research department; one research exam room for study equipment and assessments and a larger open space that served the dual function of lab

area/investigational product storage, and staff work area. The equipment was basic, and old, but still functioned well enough to provide compliant blood pressure, ECG, and spirometry results. The equipment calibration logs reflected consistency and meticulously listed the current date and manufacturer details.

The research staff retention was high and turnover was low—two important details when considering investigational site stability. The smiling faces of hardworking employees bespoke a positive work environment more important than physical presentation.

Behind the Curtain

The director informed me that the site's principal investigator (PI), though newer to the role, had completed online investigator and Good Clinical Practice training, and had strong sub-investigator experience. While he had only served as the PI on two previous studies, his CV demonstrated his therapeutic expertise. The site had also arranged for the sub-investigator, an experienced investigator in his own right, to guide the PI through the first screening visit of each study for which he had oversight. Their due diligence spoke to quality in clinical trials conduct.

The visit concluded with the PI study discussion, and I was duly impressed with the insightful protocol questions that lent credibility to the site's understanding of the study design. As I walked to the lobby with the site director, his parting words solidified my decision to recommend the site for selection. He did not ask the typical "What do you think?" or "Are you going to select us?" questions that would have left me feeling uncomfortable. He merely encouraged me to contact him with any additional questions or information required and thanked me sincerely for my time.

What didn't stick in my mind as I left was the site's location/physical appearance. What resonated with me was the high levels of professionalism, transparency, and preparation evidenced by the site director for the evaluation visit. The true site character showed a site with high potential that I would gladly recommend for our study.

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