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# Analyzing the Use of Plain Language in Brief Summaries on ClinicalTrials.gov

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# ANALYZING THE USE OF PLAIN LANGUAGE IN BRIEF SUMMARIES ON CLINICALTRIALS.GOV

by

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# ABSTRACT

ClinicalTrials.gov is a database designed to help clinical researchers make their research publicly available. The clinical trials registered on the database each include a brief summary, which is meant to be a short description that the public can easily understand. In September 2022, ClinicalTrials.gov published a "Plain Language Checklist for Lay Brief Summaries" on their website, which identifies plain language best practices intended to help investigators craft summaries that can be readily understood by the public. This thesis assesses the impact of the checklist on the language use in the brief summaries in the year following the checklist's publication. The analysis examines 62 brief summaries for Phase III and IV clinical trials posted on ClinicalTrials.gov between September 26, 2022, and September 26, 2023. It focuses particularly on summaries associated with rheumatoid arthritis, knee replacement, and conjunctivitis to gauge how well they complied with 4 of the 19 criteria on the Plain Language Checklist: keeping sentences and paragraphs short, aiming for a 6th to 8th grade reading level, writing out acronyms on the first use, and providing both percentages and natural frequencies. It also examines rhetorical moves made in the summaries to address the use of jargon, key term definitions, headings, formatted lists, direct research questions, descriptions of study type, sentence fragments, and the placement of the purpose statement to see how these moves affected the plain language. Although the summaries tended to comply with the paragraph length guidelines, they did not comply with the sentence length, reading level, or acronym guidelines. The variation in compliance could be attributed to researchers' lack of awareness of the guidelines, lack of time to devote to creating brief summaries, or being too immersed in the field to imagine the needs of a lay audience. It could also be attributed to the National Institute of Health not enforcing the guidelines or to researchers not viewing the guidelines as being relevant.

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"Plain language" is commonly understood language that is easy for a public or nonspecialist audience to understand (Evans, 2020). A document is in plain language if its readers can easily find the information they need, understand it, and use it (Clarity International, 2024; International Organization for Standardization, 2023; International Plain Language Federation, n.d.; Plain Language Action and Information Network, n.d.). This definition of plain language is reader-centered rather than writer-centered (International Organization for Standardization, 2023). It focuses on how the final written document impacts the audience, asking if the document is organized, clear, and usable.

To better explain what plain language is and why it is significant, it is useful to consider briefly what plain language is *not*. Plain language is not oversimplified or dumbed-down language, it is not language that is imprecise, and it is not impossible to use with technical subjects (Chamberlain & Drees, 2021). Instead, "the goal [of plain language] is clear, effective communication" (Thornley).

Medical writers Lisa Chamberlain James and Barry Drees (2021) explain that plain language can be difficult to write. Writers of plain language must think about the purpose of the document and the literacy level of their audience (which, they remind us, has nothing to do with general intelligence). Writers must be careful and selective about what they present—they can't put in everything. They must also explain results of research in a simple way and put those results into context so that readers can make sense of what the document presents.

Because the definition of plain language is reader-driven, writers sometimes do not know how to achieve plain language. As a result, many guides and checklists of writing strategies have been developed. These guides and checklists can help writers make rhetorical moves that are likely to clarify

their documents for readers. For clinical trials, one such checklist is the “Plain Language Checklist for Lay Brief Summaries,” by ClinicalTrials.gov (ClinicalTrials.gov). This checklist was published on their website on September 26, 2022 (US National Library of Medicine, 2022). The website explains, “The checklist identifies plain language best practices to help investigators write brief summaries that can be easily understood by the general public” (US National Library of Medicine, n.d.).

For this thesis, I examine the impact that the checklist has had on the language used in brief summaries on the ClinicalTrials.gov database. I specifically aim to answer the following research questions:

1. To what extent are writers who submit to ClinicalTrials.gov following the guidelines on the checklist?
2. What kinds of rhetorical moves do writers use in creating brief summaries?

To perform this introductory study, I searched ClinicalTrials.gov for Phase III and IV clinical trials first posted between September 26, 2022, and September 26, 2023. I included only trials associated with rheumatoid arthritis, knee replacement, and conjunctivitis to limit the results. A total of 62 studies were included in the analyzed data set.

To provide context for this study, I begin the rest of this introduction chapter by outlining some benefits of plain language. Next, I provide a brief history of plain language and discuss the impact of the digital age on plain language initiatives. I then briefly describe 3 science communication models and how they relate to citizen science, the impact of plain language on the medical field, and the emergence of plain language summaries in the medical field. This background information will set the stage for my own analysis of brief summaries on ClinicalTrials.gov.

## Benefits of Plain Language

Plain language can be difficult to write. However, according to the Plain Language Action Information Network (n.d., "Why") and to 2 articles by Lily Whiteman (2000a; 2000b), plain language has many benefits for readers, writers, and the scientific community.

For readers, plain language makes documents quicker and easier to read, understand, and remember. If readers can understand the content of the documents, they can make better decisions because they are better informed. If patients are looking at plain language titles and summaries on ClinicalTrials.gov, they can better understand if a given trial is of interest to them.

Plain language can also benefit writers and the companies who pay them. Companies who write their documents in plain language save money, receive fewer calls for explanations, get their message across in the shortest time possible, and reduce the risk that the documents will be misunderstood. With plain language, companies can help their clients comply more accurately and quickly with requirements. They also help clients make fewer errors on forms. Plain language increases the potential range of readers that a company can appeal to. It also increases the chances that the reader will read more. Additionally, readers would be more likely to buy a product or ask their doctor to prescribe them a certain medication if they better understood how that product or medication could help them.

Plain language is also helpful to the scientific community. It bridges gaps between specialized disciplines. If scientists with different specialties better understood each other's research, they could more easily work together and could potentially make more breakthroughs. It also bridges gaps between scientists and the public. If scientists presented their findings in plain language, they would be more likely to reach a public audience and convey their significant breakthroughs so that the information could spread. Spreading scientific information could increase public interest, and potentially trust, in science and improve public health literacy. If scientific research were easier for the public to understand and the

public were interested in the research, scientists would be likely to get more public funding for additional research and possibly find more people interested in participating in research.

## Brief History of Plain Language

The plain language movement began in the government in the 1970s. President Nixon and President Carter called for government documents to be written in simpler language (Plain Language Action and Information Network, 2020). President Carter wanted the government documents to be "cost-effective and easy-to-understand by those who were required to comply with them" (Plain Language Action and Information Network, 2020). More recently, President Obama signed the Plain Language Act of 2010. The purpose of this act was to promote "clear Government communication that the public [could] understand and use" (111th Congress, 2010).

Over the decades, plain language has caught on in many other fields, such as the fields of technical/professional writing (Reynolds et al., 1995), legal studies (Bivins, 2008), psychology (Kerwer et al., 2021), science (Schindler, 2022a), and healthcare (Evans, 2020; Pushparajah et al., 2018).

## Impact of the Digital Age on Plain Language Initiatives

One reason plain language has become more prominent, especially in the scientific fields, is that the digital age makes research easier to access. In the past, research journals were physically printed and mailed to journal subscribers. Some healthcare associations for which there was a membership fee sent out journals to members as part of the membership benefits. In other cases, journal subscription fees were high, so typically the only people interested in subscribing to journals were experts and researchers in a particular field.

However, the internet has changed how research is disseminated. By 2010, scientific disciplines disseminated information mainly through electronic journals (Ollé and Borrego, 2010). Now many journals, including medical journals like JAMA and BMJ, can be found online, either exclusively or in

addition to the print journals. People don't have to search through print copies of journals to find scientific information. Some articles in online journals are free. Other articles in online journals may not have free online access, but the journal's editorials and table of contents (and sometimes article abstracts) are typically available. Because the information is available online, it is more accessible to the public than ever. Search engines (such as PubMed), databases (such as MEDLINE), and indexes (such as CINAHL) can search through thousands of articles in a matter of seconds, and people can download relevant articles directly. Even common search engines, such as Google and Google Scholar, can pull up relevant research articles. In part, the move toward plain language is a piece of a larger movement from a deficit model of scientific communication toward a dialogue or participatory model.

## Science Communication Models and Citizen Science

Metcalfe (2019) studied science engagement activities recorded in a 2012 audit and analyzed them in terms of 3 theoretical models of science communication that have been described over the past 20 years. The "deficit model," first discussed in the 1980s and early 90s, says that scientists need to educate the public, transfer information about science, and promote science. It imagines that the public has a deficit of scientific knowledge that the scientists must fill. The "dialogue model" arose in the 1980s, with public unease about science. This model says that scientists need to converse with and listen to the public, and it acknowledges that the public could contribute useful knowledge to the sciences. The "participatory model" has the scientists and the public as equals who must work together to build new knowledge. This model invites scientists and the public to learn collectively and share responsibility for decision making.

Metcalf emphasized that science communication theorists have called for a move toward a participatory model for quite some time. However, her study determined that the participatory model is not emphasized as much in science engagement activities as the deficit and dialogue models. Despite

the scientific community seeming to think that the participatory model or "citizen science" is a good idea, only 6% of the substantial participatory activity in Metcalf's study had lay people researching or gathering data (p. 935). Metcalfe mentions that although the objective to "get some lay people involved in gathering data or doing research" has been largely ignored in practice and in many scientific activities, citizen science activities "are expanding worldwide, and there are international and national associations for citizen science and regular conferences about the topic" (p. 394).

The Patient-Centered Outcomes Research Institute is one organization that funds participatory research in healthcare. Members of the public must be part of the initial research planning process. Other examples of citizen science research have been presented in several studies, including studies by Reid (2019) and Luzón (2013). Reid (2019) studied how a biology lab involved secondary school audiences and the general public in building a database on the heart rates and life expectancies of different animal species, which the scientists later analyzed and presented results about. Luzón (2013), studied how the lines between professional scientists and citizens blurred in discourse on science blogs. However, as Metcalf's study indicated, while citizen science projects are becoming more common, barriers still seem to exist that prevent the public from fully participating in science research.

Although the digital age has made it possible for the public to find and read more scientific information, it does not always mean that they understand or trust it. One of the many barriers to science literacy may be scientific language that is inaccessible to the public. Afterall, "recontextualizing" (Luzón) science for the public is labor-intensive. However, "providing the public with *better access* to scientists…means it is presumably easier for the public to then engage with scientists and science" (Metcalf, 2019, p. 396). If we could break down the language barriers, more citizen science seems likely to occur.

While writing in plain language may be a deficit activity—one aimed at informing the public about science that they might not otherwise understand—Metcalf indicated that "deficit activities appear to be an important component or prerequisite for dialogue and participatory activities" (p. 397). Therefore, using plain language in scientific communication could open doors for more public dialogue about science and even public participation in scientific research.

## Impact of Plain Language in Healthcare

In addition to making scientific information more available, the digital age has opened more healthcare options. For example, telehealth is one option that allows people easy access to some healthcare services, if they need healthcare service quickly or those particular healthcare services are outside of their travel zone. Even for in-person healthcare, the digital age has expanded opportunities. Where people used to only visit the healthcare providers nearest to them, patients can now shop around. Cars and other modes of transportation make the range of physical healthcare provider offices that people can access geographically wider, and insurance searches offer long lists of in-network providers.

When people have more options, they are more likely to encounter conflicting opinions about their health conditions from healthcare specialists, so many people in the general public have turned to searching on their own for information about their own health. Bellwoar (2012), through a case study on how one young woman engaged with health-related texts, provided us insight on the wide variety of texts, both physical and digital, that patients might be consulting to understand their own health. The study showed that while the research participant was "dealing with ulcerative colitis and complications related to pregnancy" (p. 325), she interacted with discussion boards, online information, instructions, magazines, a list of physicians, online bios and pictures of physicians, a binder of materials, handouts, television episodes, web images, a book, websites, baby registries, emails, and stories. The participant

"used and discarded, read and ignored, looked at, and composed a variety of textual, visual, and oral sources" (p. 327).

Like the woman in this study, many patients can search, find, access, and read healthcare information from various sources. Many of these sources are online, such as WebMD, Wikipedia, or internet discussion boards. Patients (and possibly even healthcare professionals) may find the surplus information overwhelming. It may be difficult for them to discern what is real from what is opinion-based or, in some cases, completely incorrect. Those who are seeking credible and accurate information about specific health conditions may look to scientific journals, including healthcare journals, because those journals are published online, are searchable, and are reviewed by experts in their respective fields. This information can include reports on clinical trials. However, journal articles typically contain more professional jargon, which may be unfamiliar to the reader.

There has also been a push in the healthcare fields for written documents that patients can understand, such as informed consent forms and patient education materials. For example, the Belmont Report, a document published in 1979 containing "ethical principles and guidelines for the protection of human subjects of research," requires that human subjects of research give not only their consent, but their *informed* consent, before being allowed to participate in research. This means that research participants must receive and comprehend the important information about a research study. In short, informed consent forms for any human subjects research (including healthcare research) must be written in plain language.

Pushparajah et al. (2017) also indicate that as early as 2001, clinical practice begun to embrace concepts such as shared decision making and patient empowerment. This patient and family centered care is evidence-based practice that involves including patients and their family members' values and preferences. Pushparajah et al. point out that empowering patients to act as partners in shared decision

making is connected to information exchange, “since empowerment entails acquiring sufficient knowledge to make rational decisions” (p. 476). Bellwoar’s (2021) study gives us insight into how patients might be participating in and making decisions about their own healthcare, even without the knowledge of their healthcare providers. Evans (2020) points out that now there is a call for agencies to use plain language to promote understanding of healthcare academic education materials and patient education materials (p. 9). Schindler (2022a) states that plain language summaries “may facilitate patient-physician communication that could contribute to shared decision making” (p. 4).

## Emergence of Plain Language Summaries in Healthcare Research

Because of increased public interest in health and medical research, many healthcare research projects and publications have started to include plain language summaries. Schindler (2022a) explains that plain language summaries are “summaries of scientific articles written in easy-to-read, nontechnical language” (p. 4). Kerwer et. al (2021) add that the aim of these summaries is to “communicate scientific findings to a broader audience. Typically, these plain language summaries are about the same length as ordinary scientific abstracts, and are written by the authors themselves” (p. 2).

Plain language summaries are also included in summaries of clinical trials. These summaries serve a similar purpose. For example, ClinicalTrials.gov’s “Plain Language Checklist for Lay Brief Summaries” (US National Library of Medicine, 2022) states that the goal of the summary is to provide a “brief description that the general public can easily understand and engage with.” Their Protocol Registration Data Element Definitions for Interventional and Observational Studies (2024) similarly states that a brief summary is a “short description of the clinical study, including a brief statement of the clinical study’s hypothesis, written in language intended for the lay public.” Plain language summaries can also be called other names, such as “lay abstracts, lay summaries, translational abstracts, author

summaries or non-technical summaries" (Kerwer, 2021), as well as "brief summaries" (US National Library of Medicine, 2022).

Plain language summaries can be found in healthcare journals, on pharmaceutical company websites, and in databases of healthcare research (such as ClinicalTrials.gov) In some healthcare journals, these summaries are included at the beginning of each article, right before or right after the article's abstract. Some of the summaries are written in paragraph form, while some are written as bulleted lists. Regardless of the format, plain language summaries give an overview of the main points of the research article, like an abstract does. The abstract is written for a specialist audience, so they can quickly understand the details of the study, while the plain language summary is written for a lay audience to help them understand the major findings and their possible implications for patients. Plain language summaries tend to give fewer specific details and provide more context than abstracts do.

One well-known medical journal, Annals of Internal Medicine (2024), began in 2022 to publish video summaries of their research, meant for lay audiences. According to their website, "Annals Video Summaries showcase the focal points of selected articles and reviews in an easy-to-understand summary format using engaging animation, voiceovers, and illustrations." These videos, then, could also be considered plain language summaries in healthcare journals.

Additionally, some pharmaceutical companies include plain language summaries of research that they present on their website. These summaries tend to be longer and more detailed than plain language summaries presented in research journals. For example, the plain language summaries on Pfizer's website are typically close to 11 pages long. Unlike plain language summaries in journals, these longer summaries include infographics, charts, tables, and graphs. They help people understand research being done on specific medications. These plain language summaries empower patients to participate in informed shared decision making when discussing medication options with their physicians.

Plain language summaries also appear on publicly accessible databases of clinical research, such as ClinicalTrials.gov. According to ClinicalTrials.gov's "Plain Language Checklist for Lay Brief Summaries," "The goal is a brief description that the general public can easily understand and engage with."

While most plain language shares some guidelines (like "use short sentences" and "define acronyms on the first use"), plain language summaries look very different in different places. The genre is still in flux and has yet to stabilize according to widely accepted expectations.

## Analysis of Plain Language in Brief Summaries on ClinicalTrials.gov

The World Medical Association, an organization representing physicians from many countries, seeks to promote principles of medical ethics. In June 1964, they adopted the Declaration of Helsinki, a now well-known document that lists "ethical principles for medical research involving human subjects" (World Medical Association, 2023). Since the amendment in 2000, the declaration had stated that the design of medical studies should be made publicly available. The most recently amended version of the declaration includes 2 principles about registering, publishing, and disseminating clinical research results. Principle 35 states results of clinical trials "must be registered in a publicly accessible database." Principle 36 states, "Researchers have a duty to make publicly available the results of their research."

ClinicalTrials.gov, hosted by the National Library of Medicine, is one publicly accessible database for such trials. As of September 15, 2023, the database lists 466,069 studies from 221 countries (US National Library of Medicine, 2023). However, over time ClinicalTrials.gov shifted from tailoring information to its original audience—the public—toward using the jargon favored by experts, investors, and other healthcare stakeholders (Schindler, 2022b). This linguistic shift has been evident in the "brief summary" section of the studies on the database. On September 26, 2022, ClinicalTrials.gov announced that "A Plain Language Checklist for Lay Brief Summaries" had been added to the site's support

materials. Schindler (2022b) called the checklist “a rather tacit revolution” for ClinicalTrials.gov. He explained,

> Prior to the September announcement, ClinicalTrials.gov had supplied very little guidance on the content of brief summaries; therefore, the new guidance amounts to a major improvement. By explicitly providing a Plain Language Checklist, ClinicalTrials.gov reemphasizes the requirement that these key data fields need to be understandable to patients and the public. (p. 36)

If the data on ClinicalTrials.gov were to follow the Plain Language Checklist, more members of the public, including patients and their family members, could access and easily understand current scientific research, such as healthcare research. This could be a first step in allowing them to participate more fully in the research, moving the field of medicine toward citizen science and a participatory model. At the very least, it could help patients access more information on the research being done on their respective conditions, allowing them to participate more fully with their healthcare providers in shared decision making about matters concerning their own health.

In the remainder of this thesis, I examine to what extent and how writers are using plain language in their brief summaries on ClinicalTrials.gov. Chapter 2 outlines my methods of collecting and analyzing a set of these brief summaries published since the new checklist came out. Chapter 3 presents the results of my analysis. Chapter 4 discusses the significance of the analysis and its implications.

Throughout this thesis, I aim for my prose to reflect plain language principles (to the extent the master’s thesis genre allows). For example, I chose to write out acronyms (such as plain language summary instead of PLS). I chose to use shorter paragraphs and sentences than are common in my field. I chose to use common terms for medical conditions (such as knee replacement surgery) instead of medical terms (like TKA). In the discussion section, I chose to present my recommendations as a bulleted

list so they are easy to read through and understand. I believe adopting these principles improves the clarity and transparency of writing so that more readers can access and understand new research.

# CHAPTER TWO: METHODS OF COLLECTING AND ANALYZING THE BRIEF SUMMARIES FROM CT.GOV

This chapter describes my methods for collecting sample brief summaries from ClinicalTrials.gov, selecting therapeutic areas to limit my search results, and analyzing the quantitative and qualitative aspects of the data.

## Data Collection

The aim of this study was to determine the extent to which researchers follow the "Plain Language Checklist for Lay Brief Summaries" on ClinicalTrials.gov when writing brief summaries. The checklist was published on September 26, 2022.

My data collection methods were based on those employed by Leithold et al. (2023) to study lay titles. In their study, they collected and assessed 74 lay titles on ClinicalTrials.gov from 2021. They included only Phase II/III or Phase III clinical trials and limited the scope of their study to 4 therapeutic areas: bowel disease, dementia, chronic kidney disease, and breast cancer.

On September 30, 2023, I searched ClinicalTrials.gov for clinical trials first posted between September 26, 2022, and September 26, 2023, the one-year period after the checklist was published. I included only Phase III and IV trials because their larger size would have more relevance for a lay audience. The search yielded 3,347 results.

To limit the results of this study, I included trials associated with only 3 therapeutic areas: rheumatoid arthritis, knee replacement, and conjunctivitis. The rheumatoid arthritis search yielded 27 results. The knee replacement search yielded 17. The conjunctivitis search yielded 19. One study showed up in both the rheumatoid arthritis category and the conjunctivitis category, so the duplicate study was

eliminated from the data set. Therefore, a total of 62 studies were included in the analyzed data set. (See Appendix.) The brief summaries for all 62 results were collected for coding and analysis.

## Therapeutic Area Selection

The 3 therapeutic areas— rheumatoid arthritis, knee replacement, and conjunctivitis—were chosen because (1) I was familiar with them, (2) the conditions are common in the population, and (3) the conditions are widely varied in terms of the associated body system, the duration of the condition/disease, the common treatment type, and the ages of people commonly affected.

First, I chose these conditions because I am familiar with some of the jargon in these areas, due to previous personal and educational experience. I have an immediate family member with rheumatoid arthritis and an extended family member who had a knee replacement. I took classes on musculoskeletal anatomy and orthopedic impairments as an undergraduate. I also did a brief internship at an optometrist office in 2015, where I saw several cases of pink eye. Essentially, I likely possess a similar kind of knowledge level of these therapeutic areas as the majority of people who would be searching for and reading clinical trials. Like many patients with particular health conditions or their family members, I am not an expert, but I do have some experience and knowledge of these conditions. In this sense, I am well-positioned to do this kind of study that examines the use of plain language in healthcare information about these areas.

Second, I chose these therapeutic areas because they are common. Rheumatoid arthritis affects 18 million people worldwide (WHO, 2023). There are approximately 6 million cases of conjunctivitis in the United States per year (Azari & Barney, 2013; Cleveland Clinic, 2022). Approximately 790 thousand knee replacements are performed in the United States each year (American College of Rheumatology, 2024). Because these therapeutic areas are common, there were at least 17 studies in each area listed on ClinicalTrials.gov within the last year. In addition to the studies themselves being more common on

the database, it seems likely that common conditions are more often searched for by patients and potential research participants, the very people who could benefit from brief summaries written in plain language.

Third, I selected these therapeutic areas because they vary widely in the associated body system, the duration of the condition/disease, the common treatment type, and the ages of people commonly affected.

Rheumatoid arthritis is a disease of the immune system. With rheumatoid arthritis, a person's immune system attacks their joints. There is no cure, but treatments can help decrease pain and inflammation and help limit the impact of the disease. Over half of people with rheumatoid arthritis (55%) are over age 55 (WHO, 2023).

Knee replacement, also called "knee arthroplasty," is associated with the skeletal system. Patients undergo this surgical procedure if their knees are worn-out or injured. Like rheumatoid arthritis, knee replacements are more common for older adults. One study of 78 patients who underwent knee replacement surgery found that the patients' mean age was 64 years (Silva Souza et al., 2016).

Conjunctivitis, also called "pink eye," is associated with the sensory nervous system. Conjunctivitis is a problem caused by bacteria, viruses, or allergies (Azari & Barney, 2013). Bacterial conjunctivitis is usually a short-term condition that, for uncomplicated cases, typically resolves in 1 to 2 weeks. Bacterial conjunctivitis is treated with antibiotics, viral conjunctivitis does not usually require treatment, and allergic conjunctivitis is treated with other types of medication (topical antihistamines and mast cell inhibitors). Conjunctivitis can affect children and adults (Azari & Barney, 2013).

Table 1: Variation of Selected Therapeutic Areas

| | **Rheumatoid Arthritis** | **Knee Replacement (Knee Arthroplasty)** | **Conjunctivitis (Pink Eye)** |
|---|---|---|---|
| **Commonness** | 18 million cases worldwide | 790 thousand surgeries annually in the US | 6 million cases annually in the US |
| **Body System** | Immune | Skeletal | Nervous |
| **Duration** | Chronic, incurable | Same-day surgery | Commonly acute (though some cases are chronic) |
| **Common Treatment Type** | Managed through injected or oral medication | Surgery | Antibiotics, eyedrops, antihistamines |
| **Ages of People Commonly Affected** | 55% over age 55 | Mean age: 64 | Children and adults |

I note here that the data may have a possible bias toward an older population because both rheumatoid arthritis and knee replacement tend to be more common in older patients.

## Quantitative Data Analysis

The "Plain Language Checklist for Lay Brief Summaries," which is specific to brief summaries on ClinicalTrials.gov, includes 19 checklist items. Most of the items on the list would be difficult to measure, such as "Think about your audience." However, several items on the list could be measured objectively. For the scope of this thesis, I analyzed the following 4 of the objectively measurable criteria:

- "Keep sentences and paragraphs short. Aim for sentences of 15 words or less, and paragraphs of 3-5 sentences or less."
- "Aim for a 6th-8th grade reading level."
- "Write out the full name for acronyms on first use."
- "Give both percentages and use natural frequencies: 7 out of 10 participants (70%)."

## Qualitative Data Analysis

In addition to my inquiry about the extent to which ClinicalTrials.gov entries are following some of the plain language guidelines, I am also interested in understanding the "how" of creating plain language. Therefore, I have also analyzed some of the rhetorical strategies that writers use as they enact the guidelines.

The next chapter will outline the results of the quantitative and qualitative data analysis.

# CHAPTER THREE: RESULTS FROM ANALYZING THE BRIEF SUMMARIES FROM CT.GOV

This chapter covers the results of the quantitative and qualitative data analysis for the selected brief summaries from ClinicalTrials.gov. The quantitative data analysis section primarily looks at the extent to which the brief summaries complied with the checklist, particularly focusing on sentence and paragraph length, reading level, acronyms, percentages and natural frequencies, and purpose statements. The qualitative data section looks at the rhetorical moves writers make in the summaries, particularly focusing on jargon, key term definitions, the placement of the purpose statement, formatted lists, direct research questions, study type, sentence fragments, proofreading issues, and headings.

## Quantitative Data Analysis

This section provides data toward answering the question, "To what extent are writers who submit to ClinicalTrials.gov following the guidelines on the checklist?" The section discusses the quantitative analysis results of 4 key guidelines: sentence and paragraph length, reading level, acronyms, and percentages and natural frequencies. It also touches on a fifth guideline: the purpose statement. This guideline was not originally part of the research but purpose statements occurred so often in the brief summaries that I felt this checklist item needed to be addressed. All percentages have been rounded to the nearest whole number.

### Sentence and Paragraph Length

The maximum allowed length for a lay brief summary on ClinicalTrials.gov was 5,000 characters (National Library of Medicine, 2024). The longest of the 62 summaries assessed in this study was 2,002 characters, less than half of the maximum length.

### *Sentence Length*

The brief summaries checklist recommends using 15 or fewer words per sentence. To assess sentence length, I used Microsoft Word to count the number of sentences in each summary. In the 62 summaries that were assessed, there were 211 total sentences. I then counted the number of sentences more than 15 words and the number of sentences more than 30 words. I note here that my definition of sentence length included some sentence fragments that were never completed. These sentence fragments were used to introduce lists (such as, “It aims to answer the questions of :” [NCT05671497]) or were an entire line item in a bulleted list (such as, “ianalumab 300 mg monthly or”[ NCT05985915]). I also note here that hyphenated words were counted as single words.

The shortest sentence in the data set was 4 words, and the longest sentence was 64 words.

*Shortest Sentence: “The main questions are:” (NCT05706844)*

*Longest Sentence: “Secondary: To evaluate the general safety of the vaccine in patients with ARDs at high risk of HZ immunized with RZV and non-immunosuppressed control subjects (CG); the humoral and cellular immunogenicity of RZV in patients with ARDs at high risk of HZ compared to CG; the influence of disease treatment on vaccine response; the 12-month persistence of humoral immunogenicity and incident cases of HZ.” (NCT05879419)*

Of the 211 sentences, 152 (72%) were longer than 15 words, and 54 (26%) were longer than 30 words. Of the 62 summaries, 60 (97%) contained at least one sentence over 15 words, and 39 (63%) contained only sentences longer than 15 words.

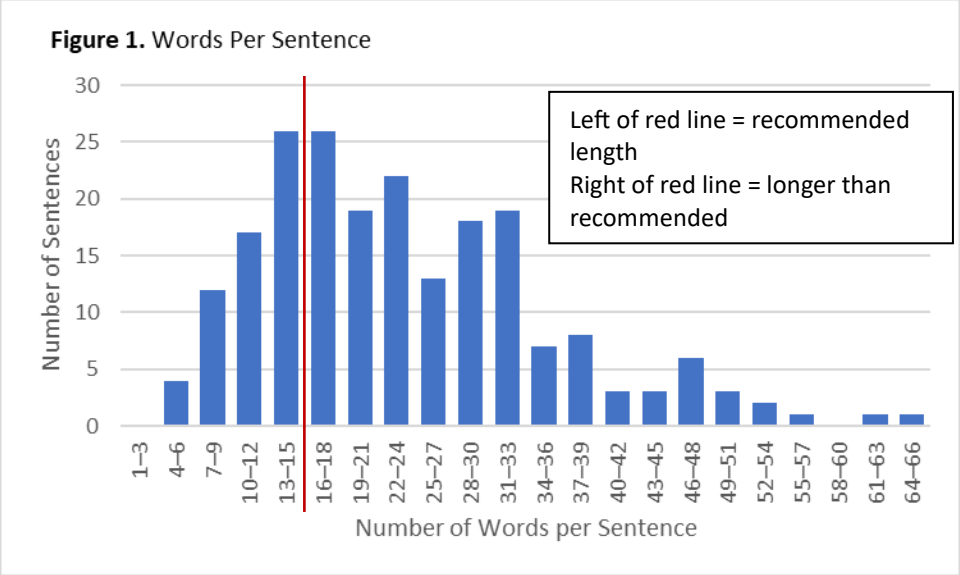

Figure 1: Words per Sentence

***Paragraph Length***

The brief summaries checklist recommends keeping paragraphs to 3–5 sentences or fewer. To assess paragraph length, I counted the number of paragraphs in each summary and the number of sentences in each paragraph. In the 62 summaries that were assessed, there were a total of 129 paragraphs. The summaries had an average of approximately 2 paragraphs each.

Of the 129 paragraphs, 107 paragraphs (83%) were fewer than 3 sentences, and 17 paragraphs (13%) were 3-5 sentences, leaving only 5 paragraphs (4%) that were longer than recommended. Eighty-nine of the 129 paragraphs (69%) were only one sentence long.

> *One-Sentence Paragraph Example: "This study aims at evaluating the possible efficacy and safety of L-carnitine in rheumatoid arthritis via targeting Jak/STAT pathway and TGF-B1" (NCT05792527)*

The longest paragraph was 10 sentences.

> *Ten-Sentence Paragraph Example: "This study assesses the impact of two differing ocular hygiene regimens prior to cataract surgery. The first regimen includes an omega-3 supplement and the second without, and both include an at-home lid wipe and cleansing eye drops. These regimens will be assessed on microbial load, inflammation, tear osmolarity, and dry eye metrics. Patients will be randomized to either the omega-3 group + 3-part hygiene regimen, or the group with only the 3-part hygiene regimen. Data will be collected for inflammation through a test (InflammaDry) that measures an inflammatory marker, dry eye metrics via an imaging tool called Oculus 5M and the Canadian Dry Eye Assessment (CDEA) questionnaire, tear osmolarity through Tear Labs device, and area of growth for conjunctiva microbial load by swabbing the conjunctiva of the eye. Dry eye metrics (CDEA and Oculus 5M) will be collected during the patient's baseline appointment, 2-5 days prior to surgery, and post-operative month 1. Microbial load swabs will be collected at baseline, 2-5 days prior to surgery, and date of the surgery. An ocular assessment will also be completed at baseline, one week post-operation, and one month post-operation. All metrics will be compared to the fellow eye. The usage of omega-3 will be compared to the regimen without omega-3." (NCT05990712)*

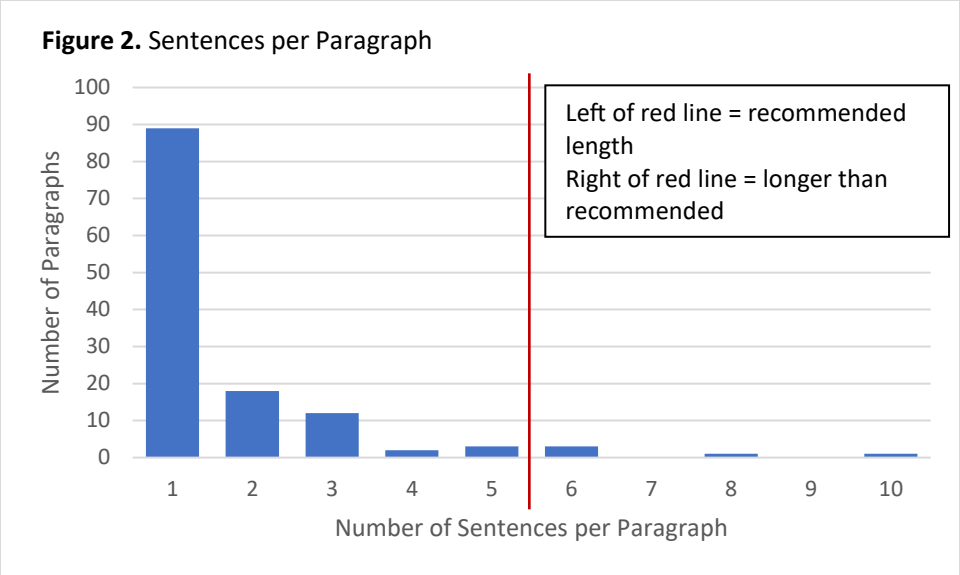


Figure 2: Sentences per Paragraph

Overall, the summaries had an average of 2 paragraphs. The paragraphs had an average of 4 sentences. The sentences had an average of 25 words. The trend within the summaries seems to be long sentences but not many sentences per paragraph.

## Reading Level

The checklist recommends that the brief summaries aim for a sixth to eighth grade reading level. I assessed reading level using the Flesch-Kincaid Grade Level score:

$$0.39 \left(\frac{\text{total words}}{\text{total sentences}}\right) + 11.8 \left(\frac{\text{total syllables}}{\text{total words}}\right) - 15.59 \quad (1)$$

A score of 8 would correspond to an 8th-grade reading level. A score of 13 through 16 would correspond to a “college” reading level. A score of 17 or above would correspond to a “college graduate” reading level.

No summaries scored less than an 8th grade reading level. One summary scored at an 8th–9th grade reading level. Two scored at a 10th-12th grade reading level. Fourteen scored at a “college” reading level. Forty-five were at a “college graduate” reading level.

*8th-9th Grade Reading Level Example: "This is a randomized controlled study. Baricitinib 4mg in one arm and Baricitinib 2mg in another arm will be used. Methotrexate 10mg per week in both arms will be used." (NCT05660655)*

*College Graduate Reading Level Example: "The purpose of this project is to determine if a change in patient reported pain, nausea and vomiting after total knee arthroplasty can be observed with the substitution of a post operative adductor canal block for a preoperative adductor canal block in the current established peri-operative pain protocol and if these changes lead to a decrease in opioid consumption (in morphine equivalents)." (NCT05974501)*

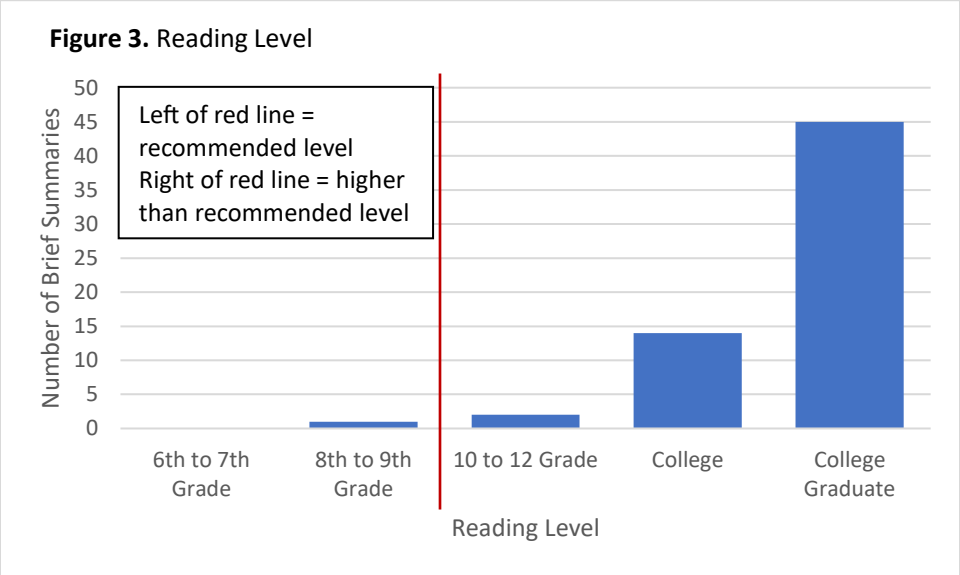

Figure 3: Reading Level

## Abbreviations, Acronyms, and Initialisms

According to *The AMA Manual of Style, 11th Edition*, an abbreviation is a shortened form of a word or phrase, an acronym is a word (pronounced as a word) that is formed from the first letter(s) of the words in the phrase, and an initialism is an abbreviation formed from initial letters and pronounced either as a word or as a set of consecutive initials (JAMA Network, 2020, pp. 555–556). Although there

are slight differences between the terms, for the purpose of this thesis, I will use "acronym" as an umbrella term to refer to all of these, since that is the term used on the checklist.

The checklist recommends defining all acronyms on their first use. The acronyms in each summary were counted. From the definition of acronyms, the following categories were excluded: names of medications, names of medical products, SI units, common Latin acronyms (like "eg," "ie," or "etc"), study acronyms, and the word "T-cell."[1]

Of the 62 brief summaries, only 35 (56%) contained acronyms. Of those summaries with acronyms, 17 (49%) defined all acronyms on the first use, 5 (14%) defined at least one acronym on the first use, and 13 (37%) did not define any acronyms on the first use.

> *All Acronyms Defined on First Use Example: "Objective To investigate the effect of Janus kinase (JAK) inhibition by baricitinib on erosion healing in rheumatoid arthritis (RA) patients with active disease using high-resolution peripheral quantitative computer tomography(HR-pQCT)." (NCT05955066, paragraph 1)*
>
> *No Acronyms Defined on First Use Example: "Aim of the Stage 2 is to confirm the efficacy and safety of levilimab 648 mg IV Q4W in combination with methotrexate and levilimab 324 mg SC Q2W in combination with methotrexate in subjects with active rheumatoid arthritis, resistant to methotrexate monotherapy." (NCT05800327, paragraph 3)*

[1] My decision to exclude the term "T-cell" has to do with the term's usage. The "T" in "T-cell" stands for thymus, but no one calls T-cells thymus cells because T-cells are immune cells that come from the thymus, thymocytes are immature T-cells that are in the thymus, and there are other epithelial cells that make up the walls of the thymus gland. Saying "thymus cell" would be confusing, especially to lay readers, because they might not know which of these cell types is being referenced. Although T-cell is technically an abbreviation, it is used more like a regular word instead of like an abbreviation.

The unique acronyms in each summary were counted and totaled. Eighty-seven acronyms were unique to their respective summaries, 57 (66%) of which were defined on the first use. One of the summaries defined at least one acronym more than once.

### Percentages & Natural Frequencies

The checklist recommends giving both percentages and natural frequencies for statistics, and it provides the example "7 out of 10 participants (70%)." The numbers in the brief summaries fit into the categories listed in Table 1. The only percentages that were included in the brief summaries were concentrations (e.g., 0.05% cyclosporine eyedrops) not statistics. The guideline to "give both percentages and natural frequencies" and the guideline to "use words and numbers to give a complete understanding" may be unneeded, since there were no statistics in the brief summaries (other than a 1 in 2 chance and 1:1 ratio—which are easy enough to understand without percentages).

Table 2: Categories of Numbers Used in Brief Summaries

| **Category** | **Example(s)** |
|---|---|
| Age | 18 years old |
| Anatomical reference | 2-4 metacarpophalangeal |
| Chemical formula | HO-1 |
| Concentration | 0.05% cyclosporine eyedrops, Ketotifen Fumarate 0.035% Ophthalmic Solution |
| Count | 2 groups, 480 participants, 250 sites |
| Fat type | omega-3 |
| Imaging tool | Oculus 5M |
| Medication/medical product/treatment | CT-P27, HS628, OC-01 nasal spray, BMS-986278, ABBV-444, SHR8028 eye drops, NOV03 |
| Name of protein/inhibitor/enzyme | TGF-B1, AVT05, TLL-018, COX-2 |
| Numbered list | It aims to answer the questions of : |

| Category | Example(s) |
|---|---|
| | 1. Will Cilostazol improve the disease severity and quality of life in Rheumatoid arthritis patients?<br><br>2. Will Cilostazol decrease the oxidative stress, inflammation and endothelial dysfunction in Rheumatoid arthritis patients? |
| Probability/Ratio | 1 in 2 chance, 1:1 |
| Score | Disease activity score 28 |
| Stage/period | stage 1, 2 periods |
| Study name | CVAY736A2302 |
| Time measurement | 30 days, 2 weeks, 6-month duration, Q2W, 9-11 pm |
| Volume, length, or mass measurement | 2 mL, 5-meter walking test, 25 mg |

## Compliance with the Four Focal Guidelines

Below is a table of the compliance of the summaries in the 4 analyzed checklist categories.

Table 3: Compliance of Summaries in Checklist Categories

| Criteria | Number of summaries in compliance/number of summaries (percentage) |
|---|---|
| Sentence length | 2/62 (3%) |
| Paragraph length | 57/62 (92%) |
| Reading level | 1/62 (2%) |
| Acronyms | 17/35 (49%)[a] |
| Percentages and natural frequencies | n/a[b] |

*[a] Only 35 of the 62 summaries contained acronyms.*

*[b] There were no statistics in the brief summaries (other than "1 in 2 chance" and "1:1 ratio")*

## Additional Findings of Quantitative Analysis

While doing the quantitative analysis of the 4 key guidelines, I noticed one other checklist guideline that seemed to deserve additional attention because it came up often. This guideline states "explain the purpose or 'why' of the research." I counted how many of the 62 studies included a purpose statement.

### *Presence of a Purpose Statement*

I found that of the 62 brief summaries, 54 (84%) included a purpose statement. There were several terms used in the purpose statement to identify it as such. Of the 62 summaries, 13 (21%) used the word "purpose," 11 (18%) used "goal," 10 (16%) used "to," 9 (15%) used "this study (will)," 9 (15%) used "aim," and 6 (10%) used "objective."

One summary (2%) used both "purpose" and "aim" (NCT06042426). Three summaries (5%) used both "goal" and "aim." These 4 summaries were double counted, so the percentages do not add up to 100%.

Five of the 62 summaries (8%) implied but did not state the purpose explicitly. Only 3 of the summaries (5%) did not state the purpose at all.

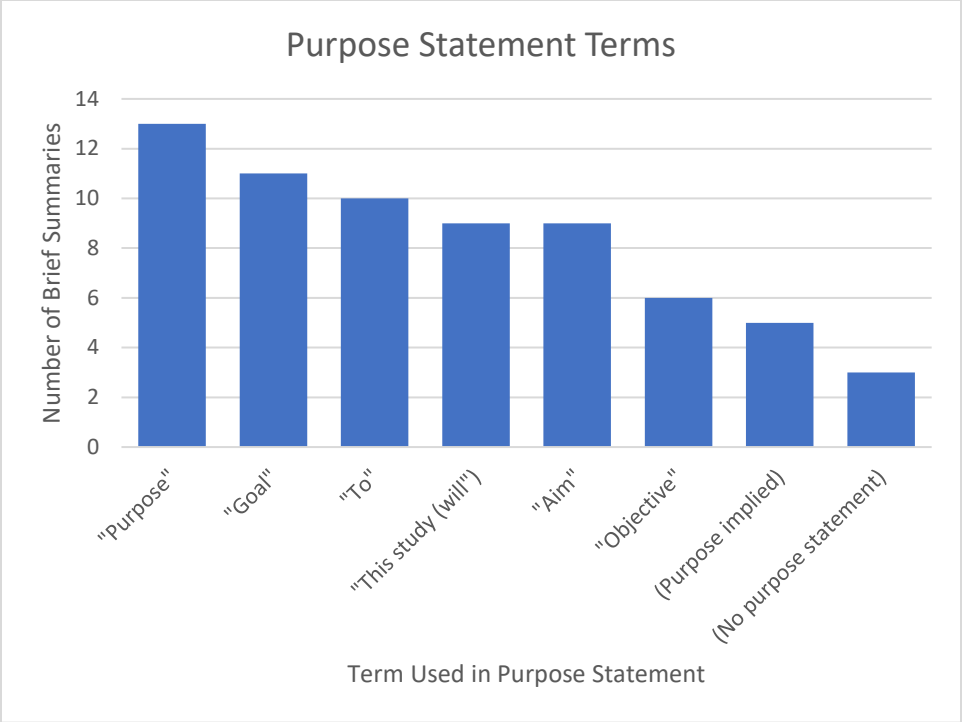


Figure 4: Terms Used in Purpose Statement

*Example of purpose statement using the term "purpose": "The purpose of this study is to assess the safety and efficacy of two doses of Deucravacitinib in adult participants with Active Sjögren's Syndrome." (NCT05946941, emphasis added)*

*Example of purpose statement using the term "to": "This is a study to compare the efficacy, safety and immunogenicity of AVT05 versus EU-Simponi® in combination with methotrexate (MTX) in subjects with moderate to severe rheumatoid arthritis (RA)." (NCT05842213, paragraph 1, emphasis added)*

Including a purpose statement is perhaps common because researchers can often reuse the purpose statement from their abstract or introduction. They already wrote it, so it's easy. Researchers are required to include a purpose statement in their abstract or intro, so they are used to including it in their work, and they know what one should sound like.

## Qualitative Data Analysis

This section provides data toward answering the question, "What kinds of rhetorical moves do writers use in creating brief summaries?" The section offers my qualitative results on additional rhetorical moves that I found in the selected brief summaries through open coding and mentions whether those moves might be useful in achieving plain language. In the rest of this chapter, I discuss rhetorical moves involving jargon, key term definitions, the placement of the purpose statement, formatted lists, direct research questions, study type, sentence fragments, proofreading issues, and headings.

### Jargon

The checklist recommends that writers "replace complex terms with common, everyday words" and "define essential jargon using common words." It is difficult to determine which terms count as health or medical jargon for a lay audience, partially because we don't have much data on which terms a lay audience can and cannot understand and partially because the health literacy level of members in a lay audience can vary widely. Although the jargon would be difficult to analyze quantitatively, it was evident that at least some level of jargon was present in most, if not all, of the brief summaries. For example, the following summary contains terms that most people in a lay audience would be unfamiliar with.

> *Example of Jargon: Aim of the Stage 1 is to study the tolerability, safety, immunogenicity, and main pharmacokinetic and pharmacodynamic parameters of levilimab after its single subcutaneous or intravenous administration at ascending doses to healthy subjects.*
>
> *(NCT05800327, paragraph 2, emphasis added)*

Some common categories of jargon terms included medication names (such as cilostazol, methotrexate, and tofacitinib), medical terms (such as glucocorticoids), undefined abbreviations (such as Q4W and

AVT05), terms about study type (such as open label, pragmatic, and superiority), and terms about study design (such as double-blinded, positive-controlled, phase 3).

Some of the jargon terms seemed necessary because they do not have a "common, everyday" synonym. This is often the case for medication or medical device names, such as "CT-P47 auto-injector" in the example below:

> *Example of Necessary Jargon Terms: "This is a phase 3 study to evaluate the usability of the CT-P47 auto-injector in patients with moderate to severe active rheumatoid arthritis."*
>
> *(NCT05725434)*

Other terms, however, could have easily been replaced with "common, everyday words." For example, the word "postoperative" can be replaced with the phrase "after surgery."

Sometimes phrases pair words that can be simplified with words that cannot be simplified. For example, in the phrase "methotrexate monotherapy," "methotrexate" is the name of a specific type of medication, so it cannot be replaced, but "monotherapy" has enough context that it can be replaced with the word "alone" to indicate that methotrexate is the only medication being used.

Other techniques to simplify language include:

- Eliminating placeholder phrases that don't hold meaning (like "there are" and "is there")
- Shifting key terms toward the beginning of the sentence (like making "baricitinib" the second word in the sentence instead of the ninth)
- Using active verbs instead of nouns when possible (like "to treat" instead of "treatment")

When combined with replacing jargon with everyday words, these techniques typically reduce the word count. For example, by using these rhetorical techniques, we can simplify the language and reduce the word count of the sentence below by 8 words without significantly changing the meaning.

*Example: "Is there any difference in the efficacy of baricitinib as monotherapy in comparison to methotrexate monotherapy or methotrexate-baricitinib combination in the treatment of rheumatoid arthritis" (NCT05827497).*

*Revised example: Is baricitinib alone more effective than methotrexate alone or methotrexate and baricitinib combined to treat rheumatoid arthritis?* (See Appendix B.)

Overall, jargon seems to make brief summaries more difficult to understand. If writers were aiming to use plain language in their brief summaries, they could reduce (though probably not eliminate) the jargon they use. If they combine reducing jargon with other techniques to simplify language, they could also reduce the summary's word count, which would make the language even more suitable for a lay audience.

**Key Term Definitions**

The checklist also recommends that writers "define essential jargon using common words." Again, it was difficult to objectively determine what counted as "essential jargon" in the summaries, so this analysis would be difficult to quantify. However, I did pick out at least 7 summaries in the dataset that provided some definitions of key terms. The definitions were typically in a sentence by themselves instead of embedded in longer sentences. The definition sentences started with the key term and ended with the definition, as in the example below, which defines "total knee replacement surgery," "glucocorticoids," and "Medrol Dose Pak."

*Example Defining Key Terms: "<u>Total knee replacement surgery</u> is a commonly performed and widely successful surgery to improve mobility and decrease pain in patients suffering from severe knee arthritis. However, in the immediate period after knee replacement, patients often experience significant pain and nausea, which can limit early recovery after surgery. <u>Glucocorticoids</u> are anti-inflammatory drugs that can reduce pain and swelling by blocking the*

*inflammatory process, and have already shown promise in various surgical settings, including after knee replacement. There are different glucocorticoid formulations available, and in this particular study, we are evaluating the effects of administering a Medrol Dose Pak, which is a commonly available glucocorticoid taper that is administered over a short period of time after surgery. Our hypothesis is that the administration of the Medrol Dose Pak will lead to decreased pain, nausea, and opioid consumption in the weeks following total knee replacement." (NCT05859269)*

In the brief summaries that felt most appropriate for a lay audience, the purpose statement always occurred after the key terms were defined, as in the example above. These summaries tended to be longer overall. Despite their length, summaries that defined key terms seemed better suited for a lay audience than ones that did not.

**Placement of the Purpose Statement**

As mentioned before, 54 of the 62 (87%) brief summaries included a purpose statement. Forty-three of those summaries placed the purpose statement in the first sentence of the summary. However, the summaries that started this way were less likely than summaries that placed the statement later to provide context for a lay audience or define key terms. The entries that defined key terms most included a clear statement of purpose but defined the key terms first.

*Example of Key Terms Defined before Purpose Statement: "Dry Eye Disease (DED) is a condition where the tear film of the eye becomes unstable and along with ocular surface inflammation and damage leads to inadequate tear production and eye lubrication. This study will evaluate symptom relief and tolerability of ABBV-444 eye drops in adult participants." (NCT05878067, paragraph 1)*

The summaries that placed the purpose statement after the key terms were defined, seemed best suited for a lay audience because the audience would first gain an understanding of the necessary context of the purpose statement.

### Formatted Lists

Eight of the brief summaries (13%) contained formatted lists. However, there seemed to be enough nuance to the purpose of the lists that further qualitative analysis was warranted. In looking closer at the lists, most of the time the lists were used to indicate the research questions. Below is an example:

> *Example List of Research Questions: The main questions are:*
>
> ** Are more patients able to be safely mobilized within 6 hours postoperatively when using GA compared to SA?*
>
> ** Does postoperative pain, nausea and vomiting, dizzyness, occurence of delirium and urinary retention differ between the anaesthetic methods? (NCT05706844, paragraphs 3–5)*

One list contained 1 study question, 3 lists contained 2 study questions, and 1 contained 5 study questions. The lists helped the questions stand out from the rest of the text and also helped readers easily see how many study questions there were.

One "list" used a bullet point in the middle of a sentence to indicate the study's main outcome of interest.

> *Example of Bullet Point in the Middle of a Sentence: The main outcome of interest is:*
>
> - *the need for re-operation for a wound complication or an infection of the prosthetic joint within one year after surgery. (NCT05828810)*

This list (defined as such because it contained an indented bullet point) included only the one bulleted item. Although it is not standard to use bullet points in the middle of a sentence, nor is it typical to use a bullet point to list only one item, the bullet in this example seemed to serve a similar function as in the lists of questions—to visually highlight key information. This use of a bullet point seems like it would help the audience identify the most important part of the study. However, readers might feel that the bullet point is less interruptive if the writer were to use a bullet point for the whole sentence instead of placing the bullet in the middle of the sentence.

Two lists were used to indicate different study arms or treatments. In this context, the lists served a different purpose. They functioned to make the different arms or treatments visually parallel so readers could compare them more easily. These lists always included at least 2 items.

The last formatted list had an asterisk for the study type, an asterisk for the study duration, and an asterisk for the frequency of treatment. Although these items were not meant to be compared, the list again kept this key information about the study parallel and helped readers to easily find it.

The lists were not all formatted the same way. Some of the lists used numbers, some used bullet points, and some used the asterisk symbol. There were no apparent patterns in which list type was used.

I did not find any numbered run-in lists. There were additional lists of items in a series, but these lists were contained within sentences or paragraphs with the items separated by commas, as in the example below:

> *This study also evaluates the anti-RANKL effect of single dose of Denosumab in serum, skeletal muscle, synovium, fat, and cartilage. (NCT05559268)*

These types of were not printed with one item below the other and were, therefore, not considered "formatted" lists. While these lists presented similar items in a parallel structure, they did not emphasize

those items with formatting, nor did they present the items in a way that they could be easily visually compared.

### Direct Research Question

Six of the brief summaries stated the research question directly, rather than not stating the question at all or stating the question indirectly. All of the directly stated research questions were formatted as a list. In the brief summary that contained only one directly stated research question, the question repeated the same information as the summary's purpose statement but left out the details of medication amounts. In the other summaries containing direct research questions, the questions either did not repeat information from the purpose statement at all or repeated some information but offered more nuance and clarification, as in the example below:

> *Example of Directly Stated Research Questions: "The goal of this open label multicenter randomized controlled pragmatic superiority trial is to investigate the optimal treatment/tapering strategy with rituximab for patients with rheumatoid arthritis.*
>
> *"The main questions it aims to answer are:*
>
> ** What is the optimal treatment/tapering strategy for rituximab in patients with rheumatoid arthritis in terms of reducing patient reported disease impact?*
>
> ** What is the optimal treatment/tapering strategy for rituximab in patients with rheumatoid arthritis in terms of therapeutic efficacy?" (NCT06003283)*

The direct research questions seemed helpful in clarifying the aims of the study, but only when they offered something more than the purpose statement. The summaries with more than one research question seemed better suited to offer these clarifications and nuances through the directly stated questions.

## Description of Study Type

Twenty of the brief summaries described the study type. Many of the descriptions of the study type contained a long series of descriptive words (such as “randomized, double-blind, double-dummy, positive-controlled, phase 3 study” [NCT06020144] or “open label multicenter randomized controlled pragmatic superiority trial” [NCT06003283]). Long series of descriptive words can be referred to as “stacked modifiers.” Editors and writers indicate that sentences with stacked modifiers are more difficult to understand (Grissino-Mayer, 2003, p. 6; Perelman et al., 1998), so the technique of stacking modifiers seems unsuitable for a lay audience.

Other study type descriptions were simpler, containing only one adjective (such as “two-stage study” [NCT05800327], “phase 3 study” [NCT05725434], or “clinical trial” [NCT05606107]). However, the descriptions of study type that contained only one adjective used jargon that a lay audience would be unlikely to know. Overall, the study type does not seem like something a lay audience would really understand or care about.

## Sentence Fragments

As previously mentioned, one of the checklist items was to keep sentences short. However, several of the shortest “sentences” counted in this study were actually sentence fragments instead of full sentences. While these particular sentence fragments met the shortness criteria, they were problematic because they did not always convey complete or clear meaning. The shortest “sentence,” for example, (“The main questions are:” [NCT05706844]), fails to convey a complete idea. If the checklist places too much emphasis on being brief (i.e., making sentences and paragraphs short), it risks encouraging more sentence fragments, which are confusing and not helpful to a lay audience.

Another problem came up as well, that may be related to the word “brief” in the phrase “brief summary” as well as the related checklist item to keep paragraphs short. Eight of the brief summaries

consisted of a single sentence fragment—not even one complete sentence. (These summaries were again counted as "sentences" for the quantitative portion of this analysis.) The sentence fragment summaries were so brief that they seemed more like titles than actual summaries. For example, below is the entirety of one brief summary:

> *Example of Sentence Fragment Summary: Safety of an eight-day treatment with ibuprofen after primary hip and knee arthroplasties. (NCT05575700)*

These summaries did not offer definitions of key terms or provide additional context for lay readers. With summaries like these, the writers seemed confused. I'm not convinced the authors understood the purpose of the summary—to provide a "brief description that the general public can easily understand and engage with" (US National Library of Medicine, 2022). While the summaries were indeed "brief" and the paragraphs were extremely short (not even a full sentence), the summaries seemed less appropriate than some of the longer ones for lay readers. Being brief is helpful, as long as the sentences are also clear and fulfill their purpose to convey meaning to a lay audience.

### Proofreading Issues

Many of the summaries were not proofread carefully. In addition to the sentence fragments, there was missing punctuation at the end of sentences (NCT05827497, NCT05792527, NCT05756179, NCT05803135, etc.), misspelled words (NCT05598242 and NCT05706844), colons after dependent clauses (NCT05671497, NCT06003283, NCT05828810, NCT05706844, etc.), and/or unnecessary capitalization (NCT05594680, NCT05842213, NCT06025578, NCT05743764, etc.). Additionally, there were various formatting issues, such as spaces before colons or commas (NCT05671497) and indecipherable symbols (NCT05743764). Occasionally the proofreading issues made the sentence difficult to understand, as in the example below:

*Example of Proofreading Issues that Obscured Sentence Meaning: "Participants will receibed amniotic membrane extract eye drops 6 times daily and was evaluated at baseline day and day 30th." (NCT05598242, paragraph 2, emphasis added)*

However, most of the proofreading issues were merely distracting and did not obscure the meaning of the summary. Although these proofreading issues did not often detract from the meaning, they could indicate that the summaries were written quickly, were often missed during the proofreading stage of the writing process, or were not prioritized as highly as some of the other documents required in the ClinicalTrials.gov submission process.

### Headings

Three of the longer summaries used section headings, such as "Hypothesis" or "Treatment Groups" (NCT05955066, NCT05879419, NCT05985915). These summaries resembled the formatting in structured abstracts that are used in many healthcare journals. Although this rhetorical strategy was not as common as some of the others, it seemed to be helpful to both label information and break up that information into smaller, more-digestible pieces.

# CHAPTER FOUR: DISCUSSION AND IMPLICATIONS

This study was motivated by 2 key research questions. The first question was, "To what extent are writers who submit to ClinicalTrials.gov following the guidelines on the checklist?" The second was "What kinds of rhetorical moves do writers use in creating brief summaries?" The following sections will discuss each question and suggest possible changes.

## Compliance/Non-Compliance

The first question was, "To what extent are writers who submit to ClinicalTrials.gov following the guidelines on the checklist?" This research indicates that while the summaries in the data set overall complied with the paragraph length and purpose statement guidelines, they did not comply with the sentence length, reading level, or acronym guidelines.

ClinicalTrials.gov has published the Plain Language Checklist in an attempt to return to its original goal of making science accessible to the public. However, this research indicates that many of the guidelines are not being followed. The variation in compliance to the checklist items could possibly be because researchers lack awareness of the guidelines, researchers run out of time and don't prioritize the brief summaries, they are too immersed in the field to remember what a lay audience might need and understand, the checklist guidelines are not being enforced, or the guidelines are not relevant.

### Awareness

The unevenness in compliance with the checklist items suggests that perhaps it is an issue of awareness—do researchers know that these guidelines exist? Upon further examination of ClinicalTrials.gov, I discovered that the checklist is not posted on the database's home page and is not attached to the guidelines webpage called "ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies." Instead, it can only be found on the

ClinicalTrials.gov announcements page under the date it was published or by searching for the title on a search engine. If writers do not know to look for the checklist, it is unlikely they will find it. Because the checklist is difficult to stumble upon if you are not searching for it directly, it seems likely that many researchers may not be aware of the guidelines. Additionally, guidelines for clinical trial grant funding are updated regularly, and criteria get missed.

If the National Institute of Health would like to promote plain language initiatives on ClinicalTrials.gov, they may want to consider making the guidelines more visible on their website to raise researcher's awareness of their desire to return to a database suitable for lay audiences. Further research could be conducted on whether the guidelines are being given adequate visibility on key pages on ClinicalTrials.gov.

Additionally, one researcher informed me that the plain language summary is only in a part of the National Institute of Health grant funding packet that no one looks at unless the grant proposal gets funded. If the National Institute of Health wanted to further promote plain language, they could move the plain language summary to earlier in their submission process to show that they prioritize it.

### Overwhelmingness

Another possible reason why compliance to the checklist may be low in some areas is that researchers submitting federal grants are overwhelmed by the number of documents they must write. Dozens of documents are submitted with federal grants, some of which are brief, while others are detailed with study design, measurement, and statistical plans. One researcher informed me that the current submission she is working on for her upcoming National Institute of Health grant currently has 50 files, which have taken months to write and revise. Researchers may simply run out of time to write and revise the brief summary because it is one of the many files that is not part of the peer review and scoring process to determine grant funding. The majority of the researchers' time typically goes into the

grant proposal and budget. Following guidelines on the Plain Language Checklist requires researchers to spend more time when registering clinical trials on ClinicalTrials.gov. The checklist adds more work to the workflow.

If ClinicalTrials.gov wanted to promote plain language, they could switch to a multi-step submission process for grant proposals. A multi-step process would allow researchers time and motivation to revise their plain language summaries if the grant is funded, which could increase the quality of the summary.

### Enforcement

Although the brief summary is a required file in the grant proposal submission process, no one assesses it or provides feedback on it. Only some researchers receive feedback on their proposals at all. For researchers that do receive feedback, that feedback is not necessarily associated with the guidelines. In fact, it is unlikely that reviewers know all of the guidelines and checklists because they are volunteers, even if they are heavily trained. Because the guidelines on the checklist are not currently being enforced, people are unlikely to change their writing habits. If brief summaries are a document we wish to prioritize, it may be worth inviting reviewers (or even members of the lay public) to provide feedback on the summaries before they are published on ClinicalTrials.gov.

### Relevance

Some of the current guidelines on the checklist may be irrelevant. For example, the checklist has several guidelines for incorporating statistics. However, none of the 62 brief summaries included statistics, likely due to the tight overall word count. Additionally, some of the guidelines are redundant to basic AMA style. For example, the checklist guideline to “Give both percentages and use natural frequencies” aligns with AMA section 18.7.3 “Reporting Proportions and Percentages,” which states “Whenever possible, proportions and percentages should be accompanied by the actual numerator (n)

and denominator (d) from which they were derived" (JAMA Network, 2020, p. 973). Some of the guidelines on the checklist could be reassessed for relevance.

The list of guidelines is so long that people can't pay attention to everything. National Institute of Health could make sure the checklist contains only the most relevant recommendations for plain language because researchers can't pay attention to everything. Further consideration of the guidelines may be necessary to determine to what extent they are useful.

### Expertise

It seems like the uneven compliance with the guidelines could, at least in part, be due to how challenging it is for experts to imagine "lay" readers and why they might be reading clinical trials. In other words, experts might have difficulty thinking and writing as if they were members of the lay public. Experts can have trouble unseeing their expertise. As a result, they might have difficulty understanding what lay readers need and crafting summaries that meet that need. In order to address this issue, experts may wish to look into how members of the public are using brief summaries and why they might be looking for information on ClinicalTrials.gov. They may also wish to work with members of the lay public to craft their summaries. This move to work with the public would help science shift toward the participatory model.

### Timing

With all that said, it has only been one year since the checklist was published, which may not have been enough time for researchers to adjust their writing processes. Ongoing research in the future could examine whether the uptake of these guidelines changes over time.

## Rhetorical Moves Toward Plain Language

My second research question was "What kinds of rhetorical moves do writers use in creating brief summaries?" The answer is that writers are making many rhetorical moves, but only some of which are useful for making language plain. The moves that seemed helpful for plain language included defining key terms, placing the purpose statement after the key terms were defined, stating the research question directly, and using section headings for longer summaries. Using lists could also potentially be helpful in promoting plain language, but only if the lists work to emphasize key information that the audience might be interested in, such as the purpose of the study or the research questions. Rhetorical moves that made language less plain included using jargon without defining it, detailing the study type, using sentence fragments (i.e., trying to make the summary too brief), and not proofreading the summary.

## Recommendations

### National Institute of Health/ClinicalTrials.gov

- Rename brief summaries to "lay summaries," or "summaries for a lay audience." Currently writers are making the summaries too brief and are often missing the purpose of the brief summary. The rhetorical move to rename the study will reemphasize to writers that the summaries are meant for non-expert audiences.
- Offer classes on lay language as a part of healthcare providers' professional development. These classes could be taught by medical writing instructors with experience in plain language or, better yet, members of the lay public.
- Check the Plain Language Checklist items for relevance to the brief summaries. Eliminate any checklist items that do not come up regularly in brief summaries.

- Put the Plain Language Checklist on a page of ClinicalTrials.gov where writers will be more likely to see it.
- Incorporate the brief summaries earlier in the submission process so that writers will know to prioritize it. Alternatively, provide a multi-step submission process so writers have adequate time to focus on the brief summary.
- Provide an easily accessible video on ClinicalTrials.gov that informs writers of the purpose of brief summaries. The video could possibly include brief interview clips from patients so that the writers can better picture who they are writing to.
- Provide examples of good brief summaries (and maybe also templates for the summaries) so writers can better understand the expectations, goals, and style of the summaries.
- Provide a list of "everyday words" to writers to assist them in the process of translating their clinical trial information into plain language. Afterall, a healthcare provider's everyday words may look a lot different than a lay audience's everyday words.

**Writers/Researchers**

- Invite patients and their family members to participate in creating brief summaries. Doing so would help writers and researchers better understand why lay audiences might read clinical trials and what kinds of information they find useful.
- Provide more context before stating the study's purpose. Remember that although sentences and paragraphs should be short, the summary itself doesn't have to be as short as most writers think. The limit for the summary length is 5,000 characters, so researchers should have space to provide additional context for their readers.
- Only state the research questions if they are not redundant to the purpose statement. If you do state the research questions, state them directly.

- Don't include the study type in the brief summary. Unlike expert audiences, lay audiences likely do not care about the study type, nor would they understand the jargon used to describe it.

### Teachers

- Teach audience awareness in writing classes to students who want to go into healthcare careers. Maybe writers struggle to move from seeing their writing as a working draft to imagining their writing as finished, polished text that lay readers might actually read.
- Teach concision strategies to help writers understand how they can make sentences and paragraphs brief, but emphasize that concision is only useful if it doesn't impede the very purpose of the document.
- Teach document design (such as the usefulness of headings and lists).
- Emphasize to writers that writing in plain language is one way to use every available means of persuasion. In other words, writing brief summaries is a rhetorical practice.

## Suggestions for Future Research

While there are limitations to this study, the study's results may indicate that researchers were either not willing to follow, did not know how to follow, or were not aware of the guidelines on the Plain Language Checklist presented on ClinicalTrials.gov. Further research may be needed to determine if the uneven compliance pattern holds for all healthcare disciplines and for the rest of the 19 criteria on the checklist.

Similar research could also be done on plain language summaries outside of those on ClinicalTrials.gov, such as written plain language summaries on pharmaceutical websites or in healthcare journals, as well as on video brief summaries (like those in *Annals of Internal Medicine*).

# APPENDIX A: STUDIES USED IN DATASET

Table 4: IDs and Titles of the 62 Studies Included in the Data Set

| ClinicalTrials.gov ID | Brief Title |
|---|---|
| NCT05559268 | Effects of Denosumab on Bone Microarchitecture After Total Knee Arthroplasty |
| NCT05563155 | Repeat Dose Steroid to Prevent Pain Relapse After Total Knee Arthroplasty in Patients With High Pain Response |
| NCT05575700 | Safety of Ibuprofen After Major Orthopaedic Surgeries |
| NCT05579730 | Evaluation of Brimonidine Tartrate/Ketotifen Fumarate Combination for the Treatment of Allergic Conjunctivitis |
| NCT05591755 | Evaluation of Brimonidine Tartrate/Ketotifen Fumarate Combination in Adults With Seasonal Allergic Conjunctivitis |
| NCT05594680 | Cilostazol and Methotrexate in Rheumatoid Arthritis |
| NCT05594745 | Treatment Regimens in Meibomian Gland Dysfunction |
| NCT05598242 | Amniotic Membrane Treatment for Hyposecretory Dry Eye |
| NCT05598242 | Amniotic Membrane Treatment for Hyposecretory Dry Eye |
| NCT05603832 | A Phase 3 Study of F14 for Management of Pain Following Total Knee Replacement |
| NCT05606107 | To Compare the Efficacy and Safety of Low-dose Glucocorticoids and Tofacitinib in Alleviating Moderate to High Disease Activity Rheumatoid Arthritis for 24 Weeks |
| NCT05626348 | The Clinical Efficacy of Immunomodulators in RA Patients |
| NCT05634759 | Enhancing the A in SAFE for Trachoma |
| NCT05635916 | Trial of Liposomal Bupivacaine for TKA |
| NCT05641272 | Clinical Trial to Evaluate the Efficacy and Safety of Polymerized, Mannan-Conjugated Dermatophagoides Allergen Extract |
| NCT05644496 | ZYNRELEF for Pain Management in Total Knee Arthroplasty |
| NCT05660655 | Efficacy and Safety of Baricitinib for the Treatment of Moderate to Severe Rheumatoid Arthritis |
| NCT05668390 | Safety and Efficacy of STALORALÂ® Birch 300 IR in a Paediatric Population With Birch Pollen-induced ARC w/o Asthma |
| NCT05671497 | The Effect of Cilostazol on Rheumatoid Arthritis Patients |
| NCT05673993 | A Study to Evaluate the Efficacy and Safety of Telitacicept in Subjects With Active Primary Sjogren's Syndrome |
| NCT05678335 | Tacrolimus for Thrombocytopenia in SS |

| ClinicalTrials.gov ID | Brief Title |
|---|---|
| NCT05692739 | Clinical Trial To Determine The Effectiveness And Safety Of Topical Insulin In Dry Eye |
| NCT05694130 | Tacrolimus Plus Glucocorticoid for Severe Thrombocytopenia in SS |
| NCT05695781 | Assessment of the Safety and Efficacy of BRM421 Ophthalmic Solutions in Dry Eye Subjects. |
| NCT05700422 | Nasal Spray Study in Sjogren's Dry Eye Disease |
| NCT05705843 | IO vs IV Vancomycin in Tourniquetless TKA |
| NCT05706844 | Spinal Anaesthesia vs. General Anaesthesia for THA, TKA and UKA |
| NCT05707234 | Virtual Reality Hypnosis in Total Knee Arthroplasty Under Spinal Anesthesia |
| NCT05715437 | Adductor Canal Block in Total Knee Arthroplasty |
| NCT05723770 | Effects of NOV03 on the Tear Film |
| NCT05725434 | A Study to Evaluate Usability of Subcutaneous Auto-injector of CT-P47 in Patients With Active Rheumatoid Arthritis |
| NCT05743764 | HU007 in Patients With Dry Eye Syndrome |
| NCT05756179 | Effect of Diosmin and Hesperidin in Treatment of Patients With Rheumatoid Arthritis |
| NCT05792527 | L-carnitine in Modulating Pain and Inflammation in Rheumatoid Arthritis |
| NCT05800327 | A Two-Stage Study of the Efficacy, Safety, Pharmacokinetics, Pharmacodynamics and Immunogenicity of Various Doses of Levilimab When Administered Intravenously and Subcutaneously to Healthy… |
| NCT05803135 | Iguratimod Combined With Tofacitinib in the Treatment of Rheumatoid Arthritis |
| NCT05814159 | A Study of Anakinra in Japanese Patients With Still's Disease (SJIA and AOSD) |
| NCT05814627 | Study to Assess Change in Disease Activity and Adverse Events of Oral Upadacitinib Compared to Subcutaneous Adalimumab in Adult Participants With Moderate to Severe Rheumatoid Arthritis |
| NCT05827497 | Baricitinib, Methotrexate as Monotherapy or Combination in the Treatment of Rheumatoid Arthritis - an Open Label Randomized Clinical Trial |
| NCT05828810 | CLinical Evaluation of ANtiseptic Skin Preparation in Revision Total Joint Arthroplasty of the Hip and Knee |
| NCT05841043 | Efficacy and Safety of SHR8028 Eye Drops for the Treatment of Dry Eye Disease |
| NCT05842213 | Comparative, Multicenter Study in Subjects With Rheumatoid Arthritis, ALVOFLEX |

| ClinicalTrials.gov ID | Brief Title |
|---|---|
| NCT05848128 | Efficacy and Safety Evaluation of Tavilermide Ophthalmic Solution for the Treatment of Dry Eye |
| NCT05859269 | Methylprednisolone Taper, Lower Extremity |
| NCT05878067 | A Study to Assess Symptom Relief and Product Tolerability of ABBV-444 Drops in Adult Participants |
| NCT05879419 | Recombinant Herpes Zoster Vaccine in Patients With Autoimmune Rheumatic Diseases |
| NCT05918406 | Phase 4 Study Evaluating the Safety of the Nasal Guide With Tyrvaya |
| NCT05924412 | Parecoxib in Total Knee Arthroplasty |
| NCT05946941 | A Study to Evaluate the Efficacy and Safety of Deucravacitinib in Adults With Active Sjögren's Syndrome |
| NCT05955066 | Effect of JAK Inhibitor on Erosion Healing in RA |
| NCT05974501 | Pre vs Post Block in Total Knee Arthroplasty (TKA) |
| NCT05980546 | Genicular and Anterior Femoral Cutaneous Nerve Blocks for Total Knee Arthroplasty |
| NCT05985915 | A Randomized, Double-blind 2-arm NEPTUNUS Extension Study to Assess the Long-term Safety and Efficacy of Ianalumab in Patients With Sjogrens Syndrome. |
| NCT05990712 | The Effect of a Pre-cataract Surgical Ocular Hygiene Regime on Microbial Load, Tear Osmolarity, Dry Eye, and Inflammatory Markers |
| NCT06003283 | Tapering of Rituximab Based on Interval Prolongation Compared to Disease Activity-guided Dose Reduction in Patients With Rheumatoid Arthritis |
| NCT06017362 | Clinical Trial To Determine The Efficacy And Safety Of Insulin Eye Drops In Dry Eye In Patients With Topical Hypotensors |
| NCT06020144 | NEW A Phase 3 Study Comparing TLL-018 to Tofacitinib in RA Subjects With Inadequate Response or Intolerance to bDMARDs |
| NCT06025578 | A Study to Evaluate the Efficacy, Safety, and Tolerability of BMS-986278 in Participants With Progressive Pulmonary Fibrosis |
| NCT06042426 | Effects of Perioperative Intravenous Dexamethasone in Clinical Outcomes After Total Knee Arthroplasty in a Hispanic Population |
| NCT06043908 | The Effect of 0.05% CsA Eye Drops on Post-refractive Surgery Dry Eye |
| NCT06048224 | NEW Phase III Clinical Trial Comparing the Safety, Efficacy, and Immunogenicity of Recombinant Anti-interleukin-6 Receptor Humanized Monoclonal Antibody Injection in Combination With Methotrexate and… |

| ClinicalTrials.gov ID | Brief Title |
|---|---|
| NCT06054750 | Testing Regional Anesthesia Techniques for Up and Early Discharge Following Knee Arthroplasty |

# APPENDIX B: TECHNIQUES FOR REDUCING WORD COUNT

**Original:** “Is there any difference in the efficacy of baricitinib as monotherapy in comparison to methotrexate monotherapy or methotrexate-baricitinib combination in the treatment of rheumatoid arthritis” (NCT05827497).

- **Remove filler word:** Is ~~there~~ any difference in the efficacy of baricitinib as monotherapy in comparison to methotrexate monotherapy or methotrexate-baricitinib combination in the treatment of rheumatoid arthritis.
- **Move the key terms toward the beginning of the sentence:** Is baricitinib as monotherapy any difference in the efficacy of ~~baricitinib as monotherapy~~ in comparison to methotrexate monotherapy or methotrexate-baricitinib combination in the treatment of rheumatoid arthritis.
- **Use common words:** Is baricitinib ~~as monotherapy~~ alone ~~any difference in the efficacy of~~ more effective ~~in comparison to~~ than methotrexate ~~monotherapy~~ alone or methotrexate~~-~~ and baricitinib ~~combination~~ combined in the treatment of rheumatoid arthritis.
- **Use active verbs:** Is baricitinib alone more effective than methotrexate alone or methotrexate and baricitinib combined ~~in the treatment of~~ to treat rheumatoid arthritis.

**Revised:** Is baricitinib alone more effective than methotrexate alone or methotrexate and baricitinib combined to treat rheumatoid arthritis?

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