OFFICE OF THE DEAN
Sri Lakshmi Narayana Institute of Medical Sciences
OSUDU, AGARAM VILLAGE, VILLIANUR COMMUNE, KUDAPAKKAM POST,
PUDUCHERRY - 605 502.
[Recognised by Medical Council of India, Ministry of Health letter No. U/12012/249/2005-ME (P -II) dt. 11/07/2011]
[Affliated to Bharath University, Chennai - TN]

Circular

Date: **13.08.2019**

Sub: Organising Value-added Course: Medical writing

With reference to the above mentioned subject, it is to bring to your notice that Sri Lakshmi Narayana Institute of Medical sciences is organizing **"Medical writing" Sep 2019 to Jan 2020**. The course content is enclosed below."

The application must reach the institution along with all the necessary documents as mentioned. The hard copy of the application should be sent to the institution by registered/ speed post only so as to reach on or before **31/08/2019**
Applications received after the mentioned date shall not be entertained under any circumstances.

Dean

DEAN
SRI LAKSHMI NARAYANA INSTITUTE OF MEDICAL SCIENCES
OSUDU, AGARAM VILLAGE,
KOODAPAKKAM POST,
PUDUCHERRY - 605 502

Encl: Copy of Course content

– Course Proposal

Course Title: Medical writing

Course Objective:

1. Introduction to Medical writing
2. To provide an overview of the process of medical writing
3. Why We Write and Why We Don't Write
4. Medical Writing as Storytelling
5. Writing Topics and Your Career
6. Important Components of a standard original research article
7. Drug Reference Program
8. Important Steps In Writing A Manuscript Including Plagiarism
9. Process Of Manuscript Preparation For Final Submission

Course Outcome: At the end of this course the student must able to write a Reseach paper and they must able to publish. they must know about clinical research documents, content for healthcare websites, health magazines, journals and news. ... This includes clinical trial data, regulatory submission documents, post approval documents, etc..

Course Audience: 2nd Year MBBS Students

Course Coordinator: Dr.G.Somasundaram,

Course Faculties with Qualification and Designation:

Dr.Jaikumar,Asso Prof, Dept of Pharmacology

Dr.Santhanalakshmi Asst Prof, Dept of Pharmacology

Course Curriculum/Topics with schedule (Min of 30 hours)

SlNo	Date	Topic	Time	Hours	FACULTY
1.	03.09.2019	Introduction to Medical writing	4-7 PM	3	Dr.Jaikumar
2	17.09.2019	To provide an overview of the process of medical writing	4-7 PM	3	
3	08.10.2019	Why We Write and Why We Don't Write	4-7 PM	3	
4	22.10.2019	Medical Writing as Storytelling	4-7 PM	3	
5	12.11.2019	Writing Topics and Your Career	4-7 PM	3	
6	19.11.2019	Important components of a standard original research article	4-7 PM	3	Dr.Santhanalakshmi
7	10.12.2019	Drug Reference Program	4-7 PM	3	
8	17.12.2019	Important steps in writing a manuscript including plagiarism	4-7 PM	3	
9	23.12.2019	Process of manuscript preparation for final submission	4-7 PM	3	
10	07.01.2020	Practical	4-7 PM	3	
			Total Hours	30	

REFERENCE BOOKS: (Minimum 2)

- The Complete Guide to Article Writing: How to Write Successful Articles for Online and Print Markets.Naveed Saleh
- How to Write Better Medical Papers. Michael Hanna

VALUE ADDED COURSE

1. Name of the programme & Code

MEDICAL WRITING

2. Duration & Period

30 hrs & **Sep 2019 to jan 2020**

3. Information Brochure and Course Content of Value Added Courses

Enclosed as Annexure- I

4. List of students enrolled

Enclosed as Annexure- II

5. Assessment procedures:

Short answers *Enclosed as Annexure- III*

6. Certificate model

Enclosed as Annexure- IV

7. No. of times offered during the same year:

Sep 2019 to jan 2020

8. Year of discontinuation: 2020

9. Summary report of each program year-wise

Value Added Course- Sep 2019 to jan 2020					
Sl. No	**Course Code**	**Course Name**	**Resource Persons**	**Target Students**	**Strength & Year**
1	PH09	**MEDICAL WRITING**	Dr.Jaikumar, Dr.Santhanalakshmi	2nd MBBS	**20&Sep 2019 to jan 2020**

10. Course Feed Back

Enclosed as Annexure- V

RESOURCE PERSON **COORDINATOR**

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY
Sri Lakshmi Narayana Institute Of Medical Sciences
PONDICHERRY - 605 502

MEDICAL WRITING
PARTICIPANT HAND BOOK

COURSE DETAILS

Particulars	Description
Course Title	**Medical Writing**
Course Code	PHA09
Objective	Introduction to Medical writing To provide an overview of the process of medical writing Why We Write and Why We Don't Write Medical Writing as Storytelling Writing Topics and Your Career Important components of a standard original research article Drug Reference Program Important steps in writing a manuscript including plagiarism Process of manuscript preparation for final submission
Key Competencies	At the end of this course the student must able to write a Reseach paper and they must able to publish. they must know about clinical research documents, content for healthcare websites, health magazines, journals and news. ... This includes clinical trial data, regulatory submission documents, post approval documents, etc.
Target Student	II MBBS Students

Duration	30hrs Every January 2020 -May 2020
Theory Session	10hrs
Practical Session	20hrs
Assessment Procedure	Short notes

Medical Writing

Medical writing involves communicating composite data and ideas in a clear, brief, plausible, absolute, and convincing manner. It's all about developing materials about medicine and health by collecting, organizing, interpreting, and presenting information in a manner appropriate for the target audience.

Life sciences graduates can deem medical writing as a valuable career choice as the demand for medical writing professionals is growing progressively in pharmaceutical and healthcare industries. In these days, there is a rapid addition of new information and knowledge related to the field of sciences and medicines in the form of research articles, clinical papers or studies or data.

Ayurveda, the oldest medical writing of Hindus, is a part of the least ancient Veda-Atharva Veda. Also, there are several other examples of ancient medical writing concepts, which include Hippocratic writings, Aristotle, Diocles, among others. They wrote about the definitions of the different diseases, their clinical symptoms, diagnosis and differential analysis. Firstly, these topics were described and then followed by a debate of the hypotheses on aetiology and pathogenesis.

Medical writing can be of several types like research writing, product related promotional writing, educational materials for patients or researchers or physicians, manuscripts, abstracts, health related news articles, regulatory, websites of healthcare or pharmaceutical companies and many others. These medical or scientific information documents should be written according to the type of target audiences like patients, doctors or physicians, general public or the regulatory officials.

A **medical writer** is a person who applies the principles of clinical research in developing clinical trial documents that effectively and clearly describe research results, product use, and other medical information. The Medical writers develops any of the five modules of the Common Technical Document. The medical writers also ensure that their documents comply with regulatory, journal, or other guidelines in terms of content, format, and structure.

Medical writing as a function became established in the pharmaceutical and contract research organization industry because the industry recognized that it requires special skill to produce well-structured documents that present information clearly and concisely. All new drugs go through the increasingly complex process of clinical trials and regulatory procedures that lead to market approval. This demand for the clear articulation of medical science, drives the demand for well written, standards-compliant documents that medical professionals can easily and quickly read and understand. Similarly, medical institutions engage in translational research, and some medical writers have experience offering writing support to the principal investigators for grant applications and specialized publications.[1][2][3]

Medical writing for the pharmaceutical industry can be classified as either *regulatory medical writing* or *educational medical writing*.

Regulatory medical writing means creating the documentation that regulatory agencies require in the approval process for drugs, devices and biologics. Regulatory documents can be huge and are formulaic. They include clinical study protocols, clinical study reports, patient informed consent forms, investigator brochures and summary documents (e.g. in Common Technical Document [CTD] format) that summarize and discuss the data a company gathers in the course of developing a medical product.

Educational medical writing means writing documents about drugs, devices and biologics for general audiences, and for specific audiences such as health care professionals. These include sales literature for newly launched drugs, data presentations for medical conferences, medical journal articles for nurses, physicians and pharmacists, consumer education and programs and enduring materials for continuing education (CE) or continuing medical education (CME). It plays a very important role in promotion of various pharmaceutical brands both to the HCPs and the consumers. Different types of communication use different media to present the writings.

Other types of medical writing include journalism and marketing, both of which can have a medical writing focus.

Regardless of the type of medical writing, companies either assign it to an *in-house* writer, or "*outsource*" it to a freelance or contract medical writer.

These organizations provide a forum where medical writers meet and share knowledge and experience. They promote professional development and standards of documentation excellence, and help writers find career opportunities. All these organizations offer fundamental medical writing training.

Where Do I Start If I Have Never Been Published? The Medical Writer's Three Questions In Puccini's opera Turandot, Princess Turandot asks Prince Calef three questions, framed as riddles. If the lovestruck prince answers the three queries correctly, he gets the princess's hand in marriage. If he fails, an early death will be the result. For medical writers, also, there are the three key questions, mentioned in the Preface to this book, that must be answered when considering a project: So what? Who cares? Where will my article be published? For the medical writer—whether neophyte or seasoned— these questions are vital. If you answer the three questions clearly, you have the best chance of success. On the other hand, if you fail to provide a convincing answer to one or more of the questions, you won't exactly lose your head, but the success of your paper is definitely in

jeopardy. So What? The medical landscape is littered with published papers that, like discarded fast-food wrappers along a country lane, have accomplished little more than adding a few lines to the Table 1.3 Some topics discussed in the ICMJE Recommendations Authorship and contributorship Editorship Peer review Conflicts of interest Confidentiality Protection of research participants Copyright Overlapping publications Fees Electronic publishing Clinical trial registration Where Do I Start If I Have Never Been Published? 26 author's curriculum vitae. If you aspire to add to the medical literature (or litter-ature), I urge you to be thoughtful in considering the "So what?" question. This question aims to determine the significance of your work. After all, undertaking a writing project is going to take you away from your patients, your family, your hobbies, or whatever else you might otherwise be doing with your time. And you are asking your audience also to commit time to reading it. So be sure the effort is worthwhile. The "So what?" questions asks: Is what I am writing about something that hasn't been said already and perhaps said better than I will say it? Am I saying anything new? Let's assume that you are a surgeon writing for a surgical journal. If you are writing an article titled "Surgical Treatment of Acute Appendicitis: A Report of 100 Cases," my first thought is that this topic may be important, but what can you say that hasn't already been said? But if your topic is "A New Surgical Technique for Appendectomy in the Patient with Acute Retrocecal Appendicitis," then you have my attention. Here is another example. One could study and report the diagnoses of the next 1000 patients seen in your office. But so what? On the other hand, if you studied the next 1000 patients seen with a presenting complaint of pelvic pain and followed them to the definitive diagnoses, then most generalists and gynecologists would be interested.

Where Will My Article Be Published? Getting an article published requires two consenting adults—an author and an editor. Of course, for refereed publications there are peer reviewers who must also nod approval. Even book publishers often have proposals reviewed by experts in the field. When you write an innovative, relevant article, you must seek the best journal for your work. Ideally you begin with a specific publication in mind, your "target journal," and then drop back to your second and third choices only if you are not successful with your first choice. Be careful with your target journal.

Some journals have such a low acceptance rate that rejection is almost guaranteed. On the other end of the spectrum, the advertiser-sponsored publications (discussed below), while lacking the cachet of the New England Journal of Medicine, need a steady supply of innovative articles and offer good opportunities for the neophyte author. Some articles, by the nature of their content, are best suited for refereed journals that publish research reports; others—such as "how-to" and "five-ways-to" Where Do I Start If I Have Never Been Published? 28 articles—are generally inappropriate for such journals, and sending them in is a waste of time. There is also the "gray literature," describing works presented at scientific meetings or as conference posters and thus being "published" as abstracts of the scientific congresses. Some Early Steps Writing Models for Beginners As a beginning author, it would be quite difficult to write a publishable report of original research on your first or second attempt. First, you need research data, which you are unlikely to have. Second, the report of original research is the most demanding of all publication models and faces the greatest competition in the publication sweepstakes. There is, however, one way that you, the relative neophyte, can actually succeed in having your name on a research report. That occurs when you are the junior member of a research team and you participate in all phases of the project, including writing the report. This approach works even better if the team includes a senior mentor, who can guide you through the process. In the absence of a research team, a seasoned mentor, and a pile of research data, what is the aspiring author to do? Plan to start with a writing model that offers the best chance of getting in print with the least need for expertise and the least risk to your ego. No, such a publication won't get you tenure or assure a lifelong career, but it will get you going. Also, it just might help you settle on a topic area that you can pursue in future writing. The leading models appropriate for neophyte writers are review articles, case reports, editorials, letters to the editor, and book reviews. All are covered in depth in later chapters of this book. The review article is appealing because advertisersupported publications, sometimes called "throwaways," have a constant appetite for content. Examples of such publications are Postgraduate Medicine, Consultant, and Hospital Practice. All have web sites for those who want to learn more. 1. Getting Started in

Medical Writing 29 Case reports are tempting and are sometimes a good way to get started as a writer. Be sure of two things: One is that you have a point to make about the case—the "So what?" question again. The second is to be sure that your target journal(s) actually publishes case reports; not all journals do so. That is the "Where will my article be published?" question once more. Editorials allow you to express opinions, and you may be an especially appropriate author for an editorial if you hold a position that gives you some expertise in the topic. For example, if you direct a pain clinic, you are qualified to write about narcotic abuse or regarding analgesic under-prescribing for patients with pain. Letters to the editor are a quick and easy way to get in print. Generally a letter to the editor comments on a published paper. What you have to say must offer new insights, and it must connect with the readers. Often such letters disagree with conclusions of the paper, and that is okay. Letters to the editor should be short and to the point. Book reviews are another opportunity for publication. Never send in an unsolicited book review. On the other hand, you can write to your favorite journal and volunteer to be a book reviewer. If added to the reviewer list, you will receive a book to review. Your job will be to write the review, as described in Chap. 7. You keep the book as payment. Book chapters are almost always invited by book editors, who try to choose prospective chapter authors from those already writing on the topic needed for the book. You may be invited to write a book chapter after publishing a few articles on your new focus area, but book chapters are usually not where a new writer begins. The same holds for writing a book. A few will succeed, but for most this is not where to start. Mistakes We Make When Getting Started • Trying to do it alone: If at all possible, work with someone more experienced. Your colleague may be a coauthor or someone who reads your work and offers comments. Where Do I Start If I Have Never Been Published? 30 • Trying to run before you can walk: Do not attempt to write the definitive treatise on a topic or the grand epic in your specialty. Aim early to learn the writing and publication process by getting something written and in print, however humble your early pieces may seem. In my early days, I wrote for Medical Economics and Physician's Management on topics such as "Having Regular Meetings with Your Office Staff" and "How to See Patients More Efficiently in Your Office." I

don't write on practice management subjects anymore, but these articles helped me learn how to write and get published. • Starting to write without preparation: It is a big mistake to begin writing until you have selected and refined your topic, figured out how you will structure your article, done your research, and assembled your writing tools. Without being prepared, inspiration won't carry you very far beyond page 1. Starting off unprepared will almost surely lead to an uneven product, and you will spend a lot of time doing remedial work. It is much better to be ready when you start and know where you are going.

Mistakes We Make When Writing Review Articles

We go wrong writing review articles in predictable ways. Since the review article is the first project many beginning medical writers undertake, I think it is useful to summarize some of the mistakes we make as neophytes. In thinking about it, some of us more experienced authors continue to make some of these errors: • Unimportant topic: Do not waste effort writing a review article on a topic that no one cares about. Field-test your idea with colleagues in the office or hospital. If you are planning to write a How to do it article on a new way to recognize borderline personality disorder or a procedure to trim hypertrophic toenails, ask several colleagues whether they might be interested in reading such an article. • Stale rehash: Be sure that you are saying something new about the topic. Step 1 is a literature search. Step 2 is a talk with a few experienceed clinicians, asking if what you propose to write about is new to them. Step 3 is a call to a journal editor. Take these steps to avoid writing an article that is not publishable because it tells nothing new. • A timely topic but already perhaps too timely: As you do your literature search, you come across an article on your topic that uses the approach you planned. You may change your approach or pick another topic. Certainly you have gained useful information. • Getting lost along the way: Make an outline with major headings, and stick to it. Don't wander off the path into irrelevant territory. • Article too long: Some editors say that this is one of the most common problems in medical writing. Why is it, with writing being such hard work, that we often overwrite? Review articles should generally be about 16–20 doublespaced manuscript pages, including references. State-ofthe-art literature reviews are

the exception and may be longer. Mistakes We Make When Writing Review Articles 170 • Too many or too few references: Avoid this mistake by studying similar articles published in your target journal. • Submission to the wrong journal: Don't waste your time— and compromise the timeliness of your article—by submitting to journals that don't publish review articles or that are likely to accept only articles written by the internationally known expert in the field.

Format for a research protocol: an expanded list of possible elements

Project title Primary investigator (PI) and coinvestigators and their institutions

Project summary: A short overview to orient the reader

Background and rationale: Analogous to the Introduction in a research report Study goals and objectives: What do you hope to accomplish?

Study design: What type of study is proposed?

Study description and methods: Who will be the subjects and what will you do to them? Safety considerations: What are the risks to subjects and what will you do about these risks?

Follow-up: What happens after the study is complete?

Data management: How will you deal with the data obtained?

Quality assurance: How will you assure that what is done reflects high standards? Expected outcomes: What do you think might be found, and why might it matter?

Dissemination of results: Who will be told about your findings?

Duration of the project: How long is each phase of the study expected to take?

Problems that may occur: What are potential difficulties and possible solutions?

Project management: In this project, who is in charge of what?

Ethical considerations: What might be ethical concerns and how will subjects be informed of these issues?

References: What are prior studies that are pertinent to this project?

Budget: What funding will be needed and how will it be used?

Informed consent forms: Forms to be read and signed by research subjects. Other support: Are there any funding sources that should be disclosed?

Collaborations planned: Will you be working with colleagues outside your designated team?

Links to other projects: Is this proposal the next step in a series of investigations?

Curriculum vitae of investigators Other research activity of investigators

Clinical trial registration status.

Project Title After deciding on a research topic/question/hypothesis, most investigators turn their attention to the project title. This is not a trivial consideration given that, when the final report is eventually published, most readers will scan the titles in the journal table of contents and use this first impression to decide whether or not to read the abstract or even the entire article. For our study, a reasonable draft title might be: "The Incidence of Low Serum Copper Levels after Gastric Surgery." Or alternatively: "Hypocupremia after Gastric Surgery." The former title tells what I wish to study and is "outcome-neutral." The latter title presumes that the outcome will be lower copper levels in gastric surgery patients and, while this may be the title of the final paper, would be presumptive as a title of a research protocol unless a question mark is added: "Hypocupremia after Gastric Surgery?" To get started I prefer the first title described. For the record, Prodan et al. titled their final, published report "Copper Deficiency After Gastric Surgery: A Reason For Caution." Acronym-named randomized trials are quite fashionable today. Clinical investigators, whimsical imps that they are, are fond of dreaming up colorful—if sometimes tortured—acro9. How to Write a Research Protocol 245 nyms, perhaps over a bottle of wine. Here is an example: "The Effect of Hydrocortisone on Development of Shock Among Patients with Severe Sepsis: The HYPRESS Randomized Clinical Trial" (Keh D et al. JAMA. 2016;316:1775). Stanbrook et al. reviewed acronym-

named clinical research trials and what happened to the reports of these studies [4]. They examined 173 consecutive randomized trials reviewed by the Cochrane Heart Group. Of these 173 studies, 59 (34%) had acronymic titles and exhibited the following characteristics: • Of these 59 studies, 61% were published in just three journals: The New England Journal of Medicine, Circulation, and The Lancet. (Recall that these were heart-diseaserelated studies). • Methodologic quality scores were higher than in studies with non-acronymic titles. • These studies enrolled five times as many patients but had shorter follow-up periods. • They were no more likely than non-acronymic-titled studies to report positive results. • They were four times as likely to have pharmaceutical financial support and eight times as likely to have industry-employed authors. I considered creating an acronym for our modest (and hypothetical) study of serum copper levels in gastric surgery patients. Thus the first title considered, "The Incidence of Low Serum Copper Levels after Gastric Surgery," would yield the acronym ILSCLAGS. Not compelling. The second choice title, "Hypocupremia after Gastric Surgery," results in HAGS. Even worse. I decided against the use of an acronymic title. When crafting a title, it is helpful to append a descriptor telling the method used, such as randomized controlled trial, case-control, cross-sectional study, or meta-analysis. Our study compares two groups, those who had weight-loss gastric surgery and those who did not. Thus our working title will be "The Incidence of Low Serum Copper Levels after Gastric Surgery: A Case Control Study." Elements of a Research Protocol 246 Primary Investigator (PI) and Coinvestigators Clearly identify the PI and all coinvestigators. Be sure to include—especially for the PI—titles, institutional affiliation, mailing addresses, telephone numbers, fax numbers, and e-mail addresses. Contact information is important, because someone may want to get in touch with you about collaboration in this study or the next or may even want to send you grant support. Project Summary Here is where you should explicitly state your research question or hypothesis. Be sure that anyone reading this paragraph has a clear idea of what you hope to learn. A good research question is short, focused, and unequivocal. Most research questions describe something that can be answered with quantitative data, although there are an increasing number of reports of qualitative research, related to topics that defy

quantification. A useful model for stating a research question is the PICO model [5]. Here is how it works and how it might apply to our study of serum copper levels: P = Population or patients: Patients who had weight-loss gastric surgery I = Indicator or intervention: Serum copper levels C = Comparator or control: Patients who did not have gastric surgery O = Outcome: Differences in serum copper levels Careful wordsmithing is vital here. Bordage and Dawson describe the research question as the "keystone of the entire enterprise," adding that, "Everything hinges on the quality of the research question, hence its crucial importance" [6]. Many RFPs specify the maximum number of pages permitted, and even if length is not prescribed, keep the Project Summary short—250 words or less and not more than one page in length. Start by using the study title, and follow by 9. How to Write a Research Protocol 247 briefly telling the rationale and objectives for the project, the research question, the methods and subjects, the duration of the study, and the anticipated outcome. Use language that would make sense to a reader who is not fully familiar with your area of inquiry. This summary page, arguably the most important page of the protocol, must give a crisp and memorable overview, and it must stand on its own, without sending the reader to search items, such as abbreviations, found later in the document. Background and Rationale This section, not unlike the Introduction section in a research report (see Chap. 11), tells why the proposed research is pertinent in the context of current knowledge. This section may cover: • The importance of the topic in the context of current knowledge • An overview of your approach to the question • Any results you have already obtained that indicate that the question can be answered by your approach • How your study will advance medical practice and the health of humankind Our serum copper level after gastric surgery study is pertinent to medical knowledge because undetected and uncorrected hypocupremia can cause health problems including anemia, neutropenia, optic neuropathy, myopathy, and myelopathy with a spastic gait [3]. You may list current references here or, alternatively, in a separate section (below). Study Goals and Objectives The WHO Recommended Format for a Research Proposal describes, "Goals are broad statements of what the proposal hopes to accomplish. They create a setting for the proposal. Elements of a Research Protocol 248 Specific

objectives are statements of the research question(s). Objectives should be simple (not complex), specific (not vague), and stated in advance (not after the research is done)" [2]. Singh et al. advise that objectives should be specific, measurable, achievable, relevant, and time based, offering the catchy acronym SMART objectives [7]. The objective of our example study might be to determine if patients who have received weight-loss gastric surgery are more likely later to have lower serum copper levels than persons who have not had gastric surgery. Study Design Describe your choice of study design—randomized trial, case-control, cohort study, cross-sectional study, or other approach—and why the study design proposed is the best way to answer the research question. For my study of serum copper levels in post-gastric surgery patients, I chose a case control study model. This and various other study design models are described in Appendix D. Study Description Here I will begin with a few linguistic tips: First of all, I recommend that you use active voice and future tense. Active voice ("We will draw blood samples" vs. "Blood samples will be drawn") is simply stronger prose. And you should use the future tense because you are describing something to be done, not something being done now or accomplished in the past. Secondly, describe persons in the study as subjects, not patients. You are not typically in a traditional physician– patient relationship with these individuals. This section of the protocol often begins by describing the subjects to be in the study and control groups. What will be your sample size? Who will be included and who will be excluded and why (think about the possibility of exclusion bias)? How did you decide on the number of subjects in each 9. How to Write a Research Protocol 249 group? A too-small sample size may not yield a statistically satisfying answer to your research question, and your study will be criticized as "underpowered." How will subjects be found? Will you use a newspaper advertisement, search existing hospital records, or use some other method? Then once you have your subjects, what will you do to them? Describe each step of the study, beginning with enrollment. If subjects are to be randomized, tell the method to be used. Continue to describe what will happen, step by step, all the way through the last follow-up event. Name the specific statistical tests that will be used to answer your research question(s) or test your hypotheses. In the case of interventional studies, it may be

useful here to identify dependent and independent variables. There are a number of statistical tests that can be used, according to the design of your study. In their published study of copper deficiency after gastric surgery, Prodan et al. used independent t tests and Fisher exact tests for comparison of continuous and categorical variables, respectively [3]. In my opinion, the diversity and complexity of the statistical tests that might be used just serve to emphasize the importance of a research team member with statistical expertise. And here is a sobering thought that will be pertinent when you write the final report of your study: According to Bordage, the most common reason manuscripts are rejected by peer-reviewed scientific journals is incomplete or inappropriate statistics [8]. Safety Considerations This section is about risks to the subjects, especially pertinent when patients will take drugs or undergo procedures. Tell the risks, including possible drug side effects, allergic reactions, or procedural complications. Then describe what you will do to reduce risk and what will happen if adverse events occur. Rid et al. have proposed a framework for assessing the risks associated with a research project [9]. They call this Elements of a Research Protocol 250 method the systematic evaluation of research risks (SERR) and base the method on four steps: 1. Identifying potential harms associated with the project 2. Categorizing the magnitude of the potential harms described 3. Quantifying or estimating the likelihood of each potential harm occurring 4. Comparing the likelihood of each potential interventionrelated harm with what might occur with a comparable activity For my study involving determining serum copper levels in study and control group subjects, I believe that the chief risks are those associated with obtaining blood samples. In the study cohort, the surgery is completed before the study begins. Follow-Up Here you should tell what, if anything, will happen to subjects after the research study is completed. In my study, patients found to have significant hypocupremia will be referred to their personal physicians for further evaluation and management. Data Management As things move along, you will accumulate data—information about subjects, consent forms, laboratory reports, tables of results, and so forth. How will these data be coded and entered into computer files? How will you assure that data are both accurate and complete? Especially when your study involves human subjects, you should tell how you will

maintain security of these data. Identify who will do these tasks, ideally the project manager on your team. 9. How to Write a Research Protocol 251 Quality Assurance You should tell how you will pay attention to the fundamentals of good clinical practice, especially important when human subjects are involved. How will you determine best practice in the conduct of the study? Will there be an independent oversight committee? Expected Outcomes The ideal clinical study will have an impact on some segment of the population. In the case of my small study on the risks of copper deficiency following gastric surgery, the results will either be helpful in alerting physicians to a potential adverse outcome of an increasingly common procedure or serve to be cautionary to patients considering gastric surgery for weight control or for other reasons. Duration of the Project Here is where you should present a timeline, which may help you identify possible bottlenecks, such as the possibility that you may not find as many qualifying subjects as anticipated. The timeline also may be useful later when writing a grant application.

ANNEXURE-II

VALUE ADDED COURSE

Participant list of Value added course: Medical Writing Course code: 09

Sl. No	Name of the Student	Register No	Signature
1	NIRMAL KUMAR B	U19MB331	
2	NISHANTHI V	U19MB332	
3	NITIN NARAYAN M	U19MB333	
4	NIVASINY P S	U19MB334	
5	NUKUVOLU NIENU	U19MB335	
6	PADMAJA T	U19MB336	
7	PAVAN KALYAN POTLURI	U19MB337	
8	PAVITHRA T	U19MB338	
9	PRABHU MANIKANDAN V S	U19MB339	
10	PRADHEEP K	U19MB340	
11	PRAKHAR GAUTAM	U19MB341	
12	PRIYADHARSHINI A	U19MB342	
13	PRIYADHARSHINI M	U19MB343	
14	PRIYANSHU KESHARI	U19MB344	
15	PULAK ACHARYA	U19MB345	
16	RAAJ SETHU VINAYACK R	U19MB346	
17	RABYA TABASUM	U19MB347	
18	RAHUL MAHESHVAR M G	U19MB348	
19	RAHUL RAJ	U19MB349	
20	RAJAGOPAL R	U19MB350	

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY
Sri Lakshmi Narayana Institute Of Medical Sciences
PONDICHERRY - 605 502.

SRI LAKSHMI NARAYANA INSTITUE OF HIGHER EDUCATION AND RESEARCH

Medical writing

Annexure - IV

Short - questions

Course Code: PH09

1. Competent of medical writer should have following qualities

good understanding of scientific pharmaceutical

terminology - language

→ drug composition

medical terminologies

2. Scope of medical writing and areas of where medical writing is mandatory.

life sciences like microbiology

biochemistry

biotechnology

environmental biology.

→ medicine

→ pharmacy

→ nutrition and dietetics.

Sri Lakshmi Narayana Institute of Medical Sciences

Affiliated to Bharath Institute of Higher Education & Research
(Deemed to be University under section 3 of the UGC Act 1956)

CERTIFICATE OF MERIT

This is to certify that PADMAJA Thas actively participated in the Value Added Course on **Medical Writing** held during **Sep2019 – Jan 2020** Organized by Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry- 605 502, India.

Dr. S.Jaikumar
Dr.J.Jayasheela
Dr.P.Santhanalakshmi
RESOURCE PERSON

Dr. Somasundaram.G
COORDINATOR

Student Feedback Form

Course Name: MEDICAL WRITING

Subject Code: **PH 09**

Name of Student: Nishanth. V Roll No.: U19MB332

We are constantly looking to improve our classes and deliver the best training to you. Your evaluations, comments and suggestions will help us to improve our performance

Sl. NO	Particulars	1	2	3	4	5
1	Objective of the course is clear					✓
2	Course contents met with your expectations					✓
3	Lecturer sequence was well planned					✓
4	Lectures were clear and easy to understand				✓	
5	Teaching aids were effective					✓
6	Instructors encourage interaction and were helpful				✓	
7	The level of the course					✓
8	Overall rating of the course	1	2	3	4	5

** Rating: 5 – Outstanding; 4 - Excellent; 3 – Good; 2– Satisfactory; 1 - Not-Satisfactory*

Suggestions if any:

SRI LAKSHMI NARAYANA INSTITUE OF MEDICAL SCIENCES AND HOSPITAL, PUDUCHERR

Date: 09.01.2020

From
Dr.G.Somasundaram
Professor and Head,
Department of Pharmacology
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry

To
The Dean,
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry.

Sub: Completion of value-added course: Medical Writing

Dear Sir,

With reference to the subject mentioned above, the department has conducted thevalue-added course titled: **Medical Writing** on **September 2019– January 2020**. We solicit your kind action to send certificates for the participants that is attached with this letter. Also, I am attaching the photographs captured during the conduct of the course.

Kind Regards

Dr.G.Somasundaram

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY
Sri Lakshmi Narayana Institute Of Medical Sciences
PONDICHERRY - 605 502