



# **Trilogy Training in Medical Writing**

## **Catalogue of Training Workshops**

## Trilogy Training Catalogue: Summary

Good medical writers are a valuable resource in short supply. They are essential resources in the production of clinical documents, which in turn are the only visible results of a clinical development programme: the basis of regulatory submissions. A medical writer requires a background knowledge and experience of scientific analysis and presentation, but also needs good training on and experience of the requirements of clinical documentation and the relevant regulatory standards.

In recognition of this need, Trilogy's training programme provides structured, workshop-style training and continuing professional development programmes for medical writers of all needs and levels of experience. Our competence in this area is drawn from our own expertise in medical writing, as well as from our experience in providing training on behalf of *EMWA (European Medical Writers Association)*, *Management Forum*, and the *DIA (Drug Information Association)*. Our courses, which are aimed at company clients providing training for their staff, give a recognised level of training, as well as meeting the audit requirements of professional development.

All Trilogy workshops are inspired by the Confucian Principle that listening is not enough to truly learn something: "I hear and I forget". To grasp new skills requires participation:

**"I see and I remember, I do and I understand"**

A key part of Trilogy training workshops are the participatory exercises involving the participants in real-life clinical documentation exercises where they can actually try out the skills being taught.

Many of our clients like us to conduct our seminars on their own site, to enable their authors (whether medical writers, study managers, pharmacovigilance writers or others) to be trained "at home" - in their own environment. We frequently arrange customised seminars - adjusting the content or duration of seminars to fit specific client needs. In addition, on-site training allows Trilogy to use examples and documents provided by the participants to illustrate many of the key principles (something not amenable to an open workshop format due to the confidentiality of clinical documentation).

All participants receive training documentation and supplementary materials for future reference.

## Categories of training

### Seminar: The Importance of documentation in presenting Clinical Trial results

This is a short “overview seminar” designed to give any members of (or entire) clinical development teams an appreciation of the challenges posed by and the inputs required for clinical documentation. As part of the development kick-off meeting it is intended to increase awareness of and demonstrate the importance of good documentation for timely submission and approval. Documentation is one of the most important results of drug development and the task of producing it is something the entire team needs to feel responsible for. In addition, good documentation with clear presentation of key results can facilitate the strategic decisions necessary for rapid and successful drug development.

### Foundation Skills for Medical Writing

Trilogy's *Foundation Skills for Medical Writing* series of training workshops are intended to provide a complete foundation for personnel new to medical writing. The workshops are structured to build on one another in chronological order to create a comprehensive foundation of skills for medical writers. New medical writers and authors taking the workshops should have previous knowledge/background in scientific analysis and presentation and, ideally, some experience of writing/formatting computer documents, as well as creating computer graphics (e.g. Word, Excel, Powerpoint).

We recommend that the full set of six half-day *Foundation Skills* workshops to be taken in two sets of three - with practical “hands-on” experience of medical writing in-between in order to consolidate the techniques learned. In this way, new medical writers can achieve a standardised level of competence on a 9 month structured programme.

### Preparing Specific Clinical Documents

Trilogy's *Specific Clinical Document* workshops are intended for medical writers with experience of clinical developments and are designed to provide the detailed knowledge required to produce the various clinical documents. Each workshop includes a review of the necessary content and message required by the individual document: how best to communicate and illustrate your message - and how best to satisfy regulation - by understanding thoroughly what regulators will be looking for.

Trilogy's *specific clinical document workshops* are designed for experienced medical writers, physicians or clinical team members facing the challenge of preparing a specific type of clinical document for the first time - or for expanding the expertise and documentation skills of experienced medical writers to cover new documentation areas.

### Strategic Communication Skills

In recognition of the important strategic function that clinical documentation has in the drug development process, Trilogy has developed a series of *Strategic Communication Skills* workshops focusing on the skills required by experienced medical writers in order to fully realize their potential as strategic partners in drug development and approval. These workshops assist participants in honing their skills in high-level summarizing, message communication and teamwork: skills critical to efficient drug development.

## Summary Overview of Trilogy Training Programme

Overview Workshop	
WS01	The Importance of Documentation in Presenting Clinical Trial Results
Complete Foundation Training Programme	
FS00	Complete Foundation Skills Programme (9 Month programme comprising units F01 to F06 below delivered in three blocks with “hands-on” experience of 4 months between each block)

Foundation Skills for Medical Writing		Preparing Specific Clinical Documents		Strategic Communication Skills	
F01	Basic Medical Writing Skills	D01	The Clinical Study Protocol (CSP)	S01	Targeting your Audience: Reviewers, Regulators, & Clinicians
F02	Data Presentation for Clinical Research (Part I)	D02	The Investigator’s Brochure (IB)	S02	Interpersonal Skills
F03	Data Presentation for Clinical Research (Part II)	D03	The Clinical Study Report (CSR)	S03	Project Management
F04	Interpretation and Presentation of Drug Safety and Efficacy Data	D04	The Paediatric Investigation Plan (PIP)	S04	Medical Writing Post-Submission and Leading to Approval
F05	Effective Use of Statistics	D05	The CTD Dossier	S05	Writing Successful Manuscripts
F06	Advanced Statistics - Graphical Analysis Techniques	D06	Safety Reports: PSUR, ASR, & RMP	S06	Effective Poster Presentations
F07	Effective reporting of scales, questionnaires and VAS	D07	Medical Writing for Observational Studies	S07	Preparing Effective Oral Communications
F08	Document review process	D08	The basics of Genetics for Medical Writers	S08	Medical Communication: Conference and Meeting Reporting

## Seminar: WS01 The Importance of Documentation in Presenting Clinical Trial Results

*An overview of the importance of clinical documentation for both writers and non-writers alike*

<b>Purpose:</b>	This seminar is designed to give entire clinical development teams an appreciation of the challenges posed by and the inputs required for clinical documentation. It is intended to increase awareness of the importance of good documentation for timely submission and approval: this is a task the entire team needs to feel responsible for.
<b>Background:</b>	Since the clinical documentation is the only part of a clinical development programme which actually gets delivered to the drug regulators, it is a key deliverable of the team. Despite this, unfortunately the needs of the documentation are often overlooked until the last minute and the job not given sufficient resources for a quality document.
<b>Scope:</b>	This seminar is designed as a briefing on the optimum process of documentation: how best to present results and distil the messages from clinical trials and communicate them to key decision makers by means of the documentation in the most effective way.
<b>Target audience:</b>	Any or all members of a clinical development team, ranging from managers and product managers, development team leaders, clinicians, statisticians, CRAs and medical writers - all involved in the development and its documentation.
<b>Seminar content:</b>	<p>The following themes are considered in the seminar:</p> <ul style="list-style-type: none"> <li>• Objectives of clinical documentation.</li> <li>• Key decision makers targeted by the documentation.</li> <li>• How best to get messages across.</li> <li>• Document structure and standards.</li> <li>• Input needed for documentation.</li> <li>• Project programme for documentation - and coordination.</li> <li>• Efficient document review.</li> <li>• Final document.</li> </ul> <p>The Trilogy trainers will analyse a document of the client's choosing and present and discuss the strengths and weaknesses to demonstrate in a practical way the principles of good medical writing.</p>
<b>Duration:</b>	2-3 hours / half day
<b>Location:</b>	Trilogy recommends that this seminar be organized at a "headquarters" location of the clinical development team as part of the kick-off process of the development project. Trilogy provides experienced trainers and materials as necessary to support training at our clients' premises.

**Training Area: Foundation Skills for Medical Writing**

**Seminar: FS00 Complete Foundation Skills Programme**

<b>Purpose:</b>	This complete foundation skills programme is designed to provide writers new to medical writing with the complete set of foundation skills necessary to enable independent production of clinical documents.
<b>Duration:</b>	One full and five half-day foundation skills seminars (modules F01 to F06) structured over a 6-month period - suggested in 2 blocks - combined with on-the job medical writing experience in the gaps between.
<b>Intended Participants:</b>	Writers new to medical writing, wishing to take a structured and complete foundation programme, as well as writers with some experience who wish to consolidate their skills and fill “skill gaps”.
<b>Recommended experience and/or previous seminars required:</b>	<ol style="list-style-type: none"> <li>1) Fluency in English language writing.</li> <li>2) Basic familiarity with clinical trials and documentation.</li> </ol>
<b>Seminar content:</b>	<p>Foundation skills modules (as described in detail in relevant seminar descriptions).</p> <p>In-between formal seminar modules, participants are assigned a Trilogy trainer to act as a mentor during their periods of hands-on medical writing experience between seminars.</p>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Produce clinical documentation independently and manage the process of review.</li> <li>• Understand the messages to be communicated and the best means of data presentation.</li> <li>• Appreciate the different audiences which documents must cater to and the needs and expectations of these different audiences.</li> <li>• Achieve a recognised and auditable level of skills training in medical writing.</li> </ul>

**Training Area: Foundation Skills for Medical Writing**

**Seminar: F01 Basic Medical Writing Skills**

<b>Purpose:</b>	To teach new medical writers the basic skills of good medical writing. Participants develop their writing style for clear and concise communication of results, objectives, and conclusions.
<b>Duration:</b>	Full day
<b>Intended Participants:</b>	Writers new to medical writing.
<b>Recommended experience and/or previous seminars required:</b>	<ol style="list-style-type: none"> <li>1) Fluency in English language writing</li> <li>2) Basic familiarity with clinical trials and documentation.</li> </ol>
<b>Seminar content:</b>	<p>This seminar explores:</p> <ul style="list-style-type: none"> <li>• Introduction to the expectations and formal standards (ICH - International Committee for Harmonisation - and GCP - Good Clinical Practice) governing medical writing and the production of clinical documentation.</li> <li>• The use of style for clear, concise writing.</li> <li>• The importance of consistency.</li> <li>• Ways to improve reader comprehension.</li> <li>• Writing for a specific audience.</li> <li>• Communicating techniques in medicine &amp; pharmacology.</li> </ul> <p>The complete full-day seminar comprises two lecture sessions, as well as 2 seminar and group practice sessions.</p>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Understand the formats and styles of documents required by clinical documentation.</li> <li>• Understand that there are different audiences and appreciate the needs and expectations of different readers: reviewers, regulators, clinical teams, management, etc.</li> <li>• Understand the basic messages which need to be made and the concise style appropriate for clear communication.</li> <li>• Develop medical writing text independently.</li> </ul>

**Training Area: Foundation Skills for Medical Writing**

**Seminar: F02 Data Presentation for Clinical Research (Part I)**

<b>Purpose:</b>	This seminar challenges and stimulates participants to think clearly about the data they present and write about, since the role of a medical writer is to present data in the clearest and most understandable form possible and data, by its very nature, is usually presented most effectively in a table or graph.
<b>Duration:</b>	Half day
<b>Intended Participants:</b>	New or experienced writers.
<b>Recommended experience and/or previous seminars required:</b>	1) Basic familiarity with clinical trials and documentation.
<b>Seminar content:</b>	<p>Participants learn about:</p> <ul style="list-style-type: none"> <li>• The basic tools of data presentation: tables and simple graphs.</li> <li>• Different types of components and presentation.</li> <li>• When - and when NOT - to use each type.</li> </ul>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Select the appropriate table or graph to communicate clearly and correctly the findings of a particular type of analysis.</li> <li>• Understand the use of tabular vs. graphical data presentation.</li> <li>• Understand how to structure a table to better communicate specific ideas.</li> </ul>

**Training Area: Foundation Skills for Medical Writing**

**Seminar: F03 Data Presentation for Clinical Research (Part II)**

<p><b>Purpose:</b></p>	<p>While clinical documents generally utilise tables and graphs, there are other, more advanced forms of data presentation with specialized uses. These presentations can be very powerful when used correctly, but are easily misused by the unwary.</p> <p>This seminar further develops the themes established in Data Presentation for Clinical Research - Part I. In particular: to broaden the discussion across a wider range of data presentation types. More tips and techniques will be presented and practiced.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Participants who have already taken seminar F03</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<ol style="list-style-type: none"> <li>1) Basic familiarity with clinical trials and documentation.</li> <li>2) Seminar FS03 or equivalent experience.</li> </ol>
<p><b>Seminar content:</b></p>	<p>In Part II participants learn about the following data presentation methods; the specialized uses of each different type, as well as rules for their optimal use:</p> <ul style="list-style-type: none"> <li>• Flow charts.</li> <li>• Pie charts.</li> <li>• Box plots.</li> <li>• Contingency tables.</li> <li>• Other specialized forms of data presentation.</li> </ul>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Appreciate the strengths and weaknesses of a range of different data presentation techniques.</li> <li>• Select an appropriate combination of data presentation types to more effectively communicate clearly and correctly the conclusion of a particular type of analysis.</li> </ul>

**Training Area: Foundation Skills for Medical Writing**

**Seminar: F04 Interpretation and Presentation of Drug Safety and Efficacy Data**

<p><b>Purpose:</b></p>	<p>This seminar explores the most informative ways of interpreting drug safety and efficacy analyses and the best ways to present and describe these results to communicate the findings. The seminar presents a general approach to the evaluation of adverse event and laboratory safety data as required when writing Clinical Study Reports and Common Technical Document submissions.</p> <p>Data safety and efficacy analyses are required in approval submissions by all regulatory authorities but they are frequently performed poorly or interpreted incorrectly. In particular, the differences between analyses for safety and efficacy data are often not properly understood and the most appropriate comparator group for different subgroups is not always apparent.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Writers with some experience, especially members of pharmacovigilance teams who are contributing to safety reports.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<ol style="list-style-type: none"> <li>1) Basic familiarity with clinical trials and documentation.</li> <li>2) Seminars F01 and F03 or equivalent experience.</li> </ol>
<p><b>Seminar content:</b></p>	<p>The seminar covers:</p> <ul style="list-style-type: none"> <li>• Strategies for identifying and reporting key safety data.</li> <li>• The important differences between the way efficacy and safety data are collected and analysed.</li> <li>• Recommendations on the best way to present these data in order to make the job of the regulatory reviewer as efficient as possible.</li> </ul> <p>This seminar uses a number of case studies to achieve its aims.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Appreciate the need for and clear difference between safety and efficacy data analyses.</li> <li>• Understand the needs and expectations of regulatory reviewers when assessing these analyses.</li> <li>• Select clear methods for presenting and communicating the results of these analyses.</li> </ul>

**Training Area: Foundation Skills for Medical Writing**

**Seminar: F05 Effective Use of Statistics**

<b>Purpose:</b>	This seminar is designed for participants who have little or no background in statistics. It is designed to build confidence and provide an “intuitive understanding” of the purpose, interpretation, and use of statistics in clinical trials and results analysis.
<b>Duration:</b>	Half day
<b>Intended Participants:</b>	Anyone writing about statistical outputs who is insecure about or unfamiliar with the statistics being used. Even writers with more experience often find the innovative approach of this seminar valuable.
<b>Recommended experience and/or previous seminars required:</b>	1) Basic familiarity with clinical trials and documentation.
<b>Seminar content:</b>	<p>The following statistical concepts are covered in depth:</p> <ul style="list-style-type: none"> <li>• Study populations.</li> <li>• Types of variables and levels of measurement.</li> <li>• Descriptive statistics.</li> <li>• Estimates and confidence intervals.</li> <li>• Sample size calculations.</li> </ul> <p>Emphasis is placed on understanding statistical presentations and reporting statistical information, not on calculations or mathematical explanations.</p>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Understand the meaning, significance and importance of statistics used in clinical trials and documentation.</li> <li>• Present and communicate the results of statistical analysis appropriately, clearly and effectively.</li> </ul>

**Training Area: Foundation Skills for Medical Writing**

**Seminar: F06 Advanced Statistics - Graphical Analysis Techniques**

<p><b>Purpose:</b></p>	<p>This seminar explores statistical graphical analysis techniques: correlation, regression, and survival (Kaplan-Meier). Correlation and regression analyses can be confusing and are frequently misunderstood as they include not only the p-value and 95% Confidence Intervals of basic statistics but also introduce the Correlation Coefficient (r) and Multiple Regression Coefficient (B). Nevertheless, these analyses are frequently used to show relationships between measured parameters and to suggest causal relationships.</p> <p>Survival analyses are frequently encountered in clinical studies of treatments for fatal diseases (e.g., oncology) where mortality is the primary variable. These analyses are the basis for understanding the efficacy of these treatments yet include a number of widely misunderstood concepts such as patient censoring, median survival and cumulative survival. In order to understand seminar participants will construct a simple Kaplan-Meier curve to better understand these curves and what they mean.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Intermediate Writers (1-2 years) with at least some exposure or expected exposure to correlation, regression or Kaplan-Meier analyses, especially members of oncology teams who are contributing to study reports.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<ol style="list-style-type: none"> <li>1) Basic familiarity with clinical trials and documentation.</li> <li>2) Seminars F02 and F03 or equivalent experience.</li> </ol>
<p><b>Seminar content:</b></p>	<p>The seminar covers:</p> <ul style="list-style-type: none"> <li>• The uses and interpretation of correlation analyses.</li> <li>• The uses and interpretation of regression analyses and how they differ from correlation.</li> <li>• The use and interpretation of survival analysis, especially the Kaplan-Meier.</li> </ul> <p>This seminar uses a number of exercises to achieve its aims.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Appreciate the use of and difference between correlation and regression analyses.</li> <li>• Understand how to write the accompanying text to both of the above analyses.</li> <li>• Understand the purpose of Kaplan-Meier analysis, how it works, and how to interpret it.</li> </ul>

**Training Area: Foundation Skills for Medical Writing**

**Seminar: F07 Effective reporting of scales, questionnaires and VAS**

<p><b>Purpose:</b></p>	<p>This seminar explains the use of assessments in outcomes that cannot easily be measured objectively. Typical examples are patient questionnaires, and physician scales: as used in areas like psychiatry and quality of Life. In addition Visual Analogue scales (VAS) are frequently used to measure pain or subjective well-being of a patient.</p> <p>These measures have some pitfalls: often producing complex results that are difficult to interpret. Nevertheless the increasing importance of patient based outcomes, quality of life and psychiatric illnesses in clinical research has made this an important aspect of medical writing.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Writers working or planning to work in areas where “soft” endpoints are often used (psychiatry, pain, QoL, health outcomes, patient focused research).</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<ol style="list-style-type: none"> <li>1) 6 months experience in medical writing.</li> <li>2) Experience of having written a study report or a manuscript based on study results or taken the respective seminars.</li> </ol>
<p><b>Seminar content:</b></p>	<p>The seminar covers:</p> <ul style="list-style-type: none"> <li>• Why “soft endpoints” are used in clinical research.</li> <li>• Typical examples.</li> <li>• How questionnaires etc. should be selected for a study, including issues of validation.</li> <li>• How to evaluate and interpret results of questionnaires, including handling of subscores and statistical analyses.</li> <li>• How to communicate results of these endpoints effectively.</li> </ul> <p>The seminar uses a number of exercises to achieve its aims.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Understand why and how questionnaires etc are used.</li> <li>• Identify areas of research where the use of these tools is useful.</li> <li>• Help selecting reasonable measures for study protocols.</li> <li>• Interpret and present results comprehensively.</li> <li>• Include results in CSRs, manuscripts and regulatory docs.</li> </ul>

## Training Area: Foundation Skills for Medical Writing

### Seminar: F08 Document Review Process

<p><b>Purpose:</b></p>	<p>Without a structured process of review, finalizing the documents required for clinical research and especially those required for regulatory marketing authorization can be a long and tortuous process.</p> <p>This seminar is designed to teach medical writers and other participants the steps and processes for a structured and effective review of their documents with all involved stakeholders in the clinical team. The goal is more efficient review and thus: higher quality documentation produced in shorter timescales.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>New or experienced writers as well as anyone involved in the clinical document review and finalization processes.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<ol style="list-style-type: none"> <li>1) Medical writing experience in document production.</li> <li>2) Experience in the challenges faced in final review and agreement of documentation with all relevant members of the clinical development team.</li> </ol>
<p><b>Seminar content:</b></p>	<p>Participants learn about:</p> <ul style="list-style-type: none"> <li>• The key steps of an effective and efficient document review processes.</li> <li>• The tools and techniques that ensure team discipline in the review process - enabling progressive agreements and lock-downs of sub-sections to lead to finalization.</li> </ul> <p>The seminar uses the review of a typical “complex” document as a case study in how to approach and manage the review process.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Plan, organise and lead document review meetings.</li> <li>• Organise and prioritise questions/comments and implement consequent changes.</li> <li>• Avoid the review process turning into a never-ending process.</li> </ul>

**Training Area: Preparing Specific Clinical Documents**

**Seminar: D01 The Clinical Study Protocol (CSP)**

<b>Purpose:</b>	This seminar prepares medical writers (who already have some experience of basic medical writing) for the challenge of preparing Clinical Study Protocols (CSPs).
<b>Duration:</b>	Half day
<b>Intended Participants:</b>	Medical writers with at least 6-8 months of experience in basic medical writing or as part of a medical writing team.
<b>Recommended experience and/or previous seminars required:</b>	1) At least 2-3 foundation skills seminars (F01-F06) or equivalent.
<b>Seminar content:</b>	<p>This seminar covers:</p> <ul style="list-style-type: none"> <li>• Consideration of the structure and contents of the document required by document standards (ICH/GCP).</li> <li>• Consideration of the needs and expectations of readers (regulators, investigating clinicians, clinical teams, reviewers).</li> <li>• Assessing what to include in the protocol and how to communicate the objectives of the proposed clinical trial.</li> <li>• Style and presentation methods.</li> <li>• Assessing how the CSP document will impact the resulting Clinical Study Report (CSR): how to ensure there are no unnecessary unpleasant outcomes or surprises.</li> <li>• Resources and where to find further help.</li> </ul>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Appreciate the different audiences which Clinical Study Protocols (CSPs) must cater to and the needs and expectations of those different audiences.</li> <li>• Understand the messages to be communicated and the best means of data presentation.</li> <li>• Produce Clinical Study Protocols (CSPs), partaking in and managing the process of review.</li> </ul>

**Training Area: Preparing Specific Clinical Documents**

**Seminar: D02 The Investigator's Brochure (IB)**

<b>Purpose:</b>	This seminar prepares medical writers with some experience of basic medical writing) for the challenge of preparing Investigator Brochures (IBs).
<b>Duration:</b>	Half day
<b>Intended Participants:</b>	Medical writers with at least 6-8 months of experience in basic medical writing or as part of a medical writing team.
<b>Recommended experience and/or previous seminars required:</b>	1) At least 2 foundation skills seminars (F01-F06) or equivalent.
<b>Seminar content:</b>	<p>This seminar covers:</p> <ul style="list-style-type: none"> <li>• A consideration of the structure and contents of the document required by document standards (ICH/GCP).</li> <li>• A consideration of the needs and expectations of readers (regulators, investigating clinicians, clinical teams, reviewers).</li> <li>• Assessing what to include in the brochure and how best to communicate it.</li> <li>• Style and presentation methods.</li> <li>• Strategies for summarising large amounts of complex data.</li> <li>• Resources and where to find further help.</li> </ul> <p>In the second part, participants will work in groups to prepare an IB outline based on actual data and compare their results to those of other groups.</p>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Appreciate the different audiences which Investigator Brochures (IBs) must cater for and the needs and expectations of those different audiences.</li> <li>• Understand the messages requiring to be communicated and the best means of data presentation.</li> <li>• Produce summaries appropriate for IBs.</li> </ul>

**Training Area: Preparing Specific Clinical Documents**

**Seminar: D03 The Clinical Study Report (CSR)**

<p><b>Purpose:</b></p>	<p>This seminar prepares medical writers (who already have some experience of basic medical writing) for the challenge of preparing Clinical Study Reports (CSRs).</p> <p>The CSR is the primary record for all clinical trials and is the basis for almost all of medical writing. Understanding the basics of the ICH requirements and knowing various approaches to the traditional problems posed by this document is critical for a medical writer to present the data appropriately and concisely.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Anyone responsible for preparing a clinical study report.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<p>1) Minimum 6 months experience of clinical development.</p>
<p><b>Seminar content:</b></p>	<p>This seminar covers:</p> <ul style="list-style-type: none"> <li>• The structure and contents of the document required current guidelines (ICH/GCP).</li> <li>• A consideration of the needs and expectations of reader communities (particularly: regulators).</li> <li>• Assessing how best to communicate the results of the clinical trial.</li> <li>• Style and presentation methods.</li> <li>• Making sure to address all the trial objectives set out in the Clinical Study Protocol (CSP).</li> <li>• Tips on best practices and things to avoid.</li> </ul> <p>Resources and where to find further guidance. This seminar presents examples and strategies developed from 15 years in medical writing, working for a wide range of pharmaceutical companies.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Make sure their CSRs are compliant with ICH guidelines.</li> <li>• Appreciate the needs and expectations of regulators when assessing CSRs and make sure that they can find all the critical information for assessment quickly, easily and clearly.</li> <li>• Understand how to communicate the data-driven messages and the best means of data presentation.</li> <li>• Effectively manage the process of review.</li> </ul>

## Training Area: Preparing Specific Clinical Documents

### Seminar: D04 The Paediatric Investigation Plan (PIP)

<b>Purpose:</b>	The seminar will familiarize participants with the EMEA's recently introduced guidance on the Paediatric Investigation Plan (PIP) Application, a new EMEA requirement designed to encourage and regulate the specific development of medicinal products for use in children.
<b>Duration:</b>	Half day
<b>Intended Participants:</b>	Anyone who needs to write a PIP.
<b>Recommended experience and/or previous seminars required:</b>	<ol style="list-style-type: none"> <li>1) Minimum 3 months experience of regulatory writing.</li> <li>2) Experience with writing Investigator's Brochures or CTD summaries would be helpful.</li> </ol>
<b>Seminar content:</b>	<p>The seminar covers:</p> <ul style="list-style-type: none"> <li>• Background information on the challenges associated with conducting paediatric development programs and the need for specific regulation.</li> <li>• The objectives of the new EMEA regulation.</li> <li>• An overview of the format and content of the documentation required for the PIP application.</li> </ul> <p>The seminar includes a discussion of Trilogy's hands-on experience with preparing PIP applications since the regulation came into effect, illustrating the logistical challenges involved in obtaining the information from teams that have little or no previous experience with this type of document.</p>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Interpret EMEA guidance on the PIP and understand the standard required for acceptance by the EMEA's Paediatric Committee.</li> <li>• Appreciate the different audiences that PIPs must cater for and the needs and expectations of those different audiences.</li> <li>• Understand the messages requiring to be communicated and the best means of data presentation.</li> <li>• Produce PIPs, partaking in and managing the process of review.</li> </ul>

## Training Area: Preparing Specific Clinical Documents

### Seminar: D05 The CTD Dossier

<p><b>Purpose:</b></p>	<p>This seminar provides experienced medical writers with an insight into the task of preparing the ultimate challenge in medical documentation Common Technical Document (CTD) Dossiers.</p> <p>CTDs are the end-product of the long and expensive clinical development process and are the sole basis of consideration for regulators considering a new drug approval.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Medical writers with at least 12 months of experience in basic medical writing or as part of a medical writing team.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<ol style="list-style-type: none"> <li>1) Minimum 12 months experience of medical writing.</li> <li>2) On-the-job experience of Clinical Trials and Clinical Study Reports (CSRs).</li> </ol>
<p><b>Seminar content:</b></p>	<p>This seminar covers:</p> <ul style="list-style-type: none"> <li>• A consideration of the structure and contents of the CTD dossier as required by document standards (ICH/GCP).</li> <li>• A consideration of the needs and expectations of reader communities (particularly: regulators and reviewers).</li> <li>• Assessing how best to distil the messages from multiple trials and CSRs and communicate the results in a coherent and consistent message for regulator consideration.</li> <li>• Style and presentation methods.</li> <li>• Tips on best practices and things to avoid.</li> </ul> <p>Resources and where to find further help. This seminar presents examples and strategies developed from 15 years in medical writing working for a wide range of pharmaceutical companies, preparing dozens of CTDs for submission worldwide.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Make sure their CTD documents are compliant with the ICH guidelines.</li> <li>• Appreciate the needs and expectations of regulators when assessing CTD dossiers and make sure that they can find all the critical information for assessment quickly, easily and clearly.</li> <li>• Understand how to communicate the data-driven messages and the best means of data presentation, in particular for across-study presentations of data.</li> <li>• Managing the process of document review.</li> <li>• Know where to go to get additional support and review assistance.</li> </ul>

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**Seminar: D06 Safety Reports: Periodic Safety Update Reports (PSURs), Annual Safety Reports (ASRs), and Risk Management Plans (RMPs)**

<p><b>Purpose:</b></p>	<p>This seminar prepares medical writers (who already have some experience of basic medical writing) for the challenge of preparing Periodic Safety Update Reports (PSURs), Annual Safety Reports (ASRs), and Risk Management Plans (RMPs).</p> <p>PSURs and ASRs are required by the regulatory authorities on a regular basis to update the worldwide safety experience with marketed drugs. Medical writers are increasingly being asked to compile such reports on behalf of pharmacovigilance departments.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Medical writers with at least 3 months of experience in basic medical writing or as part of a medical writing team.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<ol style="list-style-type: none"> <li>1) Minimum 3 months experience of medical writing.</li> <li>2) At least 2-3 foundation skills seminars (F01-F06) or equivalent.</li> </ol>
<p><b>Seminar content:</b></p>	<p>This seminar will provide a clear explanation as to what these reports are, when they need to be produced, what data should be included and how it should be presented.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Understand the messages requiring to be communicated and the best means of data presentation.</li> <li>• Produce PSURs and ASRs and manage the process of review and submission.</li> </ul>

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### Seminar: D07 Medical Writing for Observational Studies

<p><b>Purpose:</b></p>	<p>This seminar prepares medical writers (who already have some experience of basic medical writing) to write about observational (non-interventional) studies.</p> <p>Writing on this type of studies is difficult as some of the basic assumptions taken for granted in randomized controlled clinical trials are not valid. Reporting and interpretation of study results differs considerably.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Medical writers who will work on study reports, protocols and/or manuscripts about observational studies or other non-registration studies. Experience in this type of studies is not necessary.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<ol style="list-style-type: none"> <li>1) Minimum 6 months experience of medical writing.</li> <li>2) Experienced in either writing a manuscript or study report for a clinical trial.</li> </ol>
<p><b>Seminar content:</b></p>	<p>This seminar will discuss the differences between clinical trials and observational studies. Typical study designs and objectives of observational studies are presented and tips for writing protocols given. Techniques for effective interpretation and presentation of observational study data are provided.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Recognize and evaluate different types of observational studies.</li> <li>• Correctly interpret and effectively communicate results from observational studies.</li> <li>• Support the team in writing and designing meaningful study protocols.</li> </ul>

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**Seminar: D08 The basics of Genetics for Medical Writers**

<p><b>Purpose:</b></p>	<p>An understanding of genetics is becoming increasingly important in the pharmaceutical industry as the sciences of pharmacogenetics and pharmacogenomics grow and influence most aspects of drug research and development. As professional communicators, it is vital that medical writers have a basic understanding of genetics to be able to communicate the latest research and its effects correctly and effectively to regulators, healthcare professionals and even patients. Unfortunately, this area of science is often explained poorly or confusingly, and academic research papers assume a certain level of genetics knowledge.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>This seminar will give a basic understanding of genetic principles to any writer who may need to understand or write about pharmacogenetics/genomics, or with an interest or curiosity in the field. It will also be useful revision for anyone who has not been involved in the area for some time. No prior knowledge is necessary.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<p>New or experienced writers who need to understand or write about pharmacogenetics/genomics.</p>
<p><b>Seminar content:</b></p>	<p>This seminar will lead the participants through the basics of inheritance, from the behaviour of DNA in cell division, through to inheritance patterns and how these may be predicted. Advances in sequencing and advanced topics such as pharmacogenomics, medical genetics, and epigenetics will be mentioned but detailed descriptions are beyond the scope of this seminar. The correct nomenclature and syntax for medical writers will be explained (e.g. how to differentiate between genotype and phenotype).</p> <p>Participants will be assigned both pre- and post-workshop assignments.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Feel comfortable with the basic genetic terminology and nomenclature.</li> <li>• Understand, interpret and communicate about genetics research more easily.</li> </ul>

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**Seminar: S01 Targeting your Audience: Reviewers, Regulators, and Clinicians**

<b>Purpose:</b>	This seminar is intended to assist medical writers with some experience tune their documents more precisely to the needs and expectations of different reading audiences (clinicians and clinical teams, reviewers, regulators) and presents the fundamental concepts key to expressing in writing the same messages to varied audiences.
<b>Duration:</b>	Half day
<b>Intended Participants:</b>	Writers with at least 8-10 months experience with regulatory documents.
<b>Recommended experience and/or previous seminars required:</b>	<ol style="list-style-type: none"> <li>1) Familiarity with clinical trials and documentation.</li> <li>2) Experience of data presentation in medical writing.</li> </ol>
<b>Seminar content:</b>	<p>The seminar introduces, actively explores and practices the different writing styles commonly used in medical writing, emphasizing which style is most effective for each audience and document type, and why.</p> <p>Through interactive exercises, participants will learn and develop the fundamental principle of good writing: recognise who you are writing for and write for them.</p>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Appreciate the need for different style and presentation when preparing clinical documents for different audiences.</li> <li>• Understand the needs of the three main audiences in particular: clinicians and clinical teams, reviewers and regulators.</li> </ul>

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### Seminar: S02 Interpersonal Skills

<p><b>Purpose:</b></p>	<p>This seminar is intended to give more experienced writers the techniques in dealing with clinical teams in the working and social context during the preparation of clinical documentation. In particular, the seminar presents and discusses successful working style and philosophies in the social context.</p> <p>As clinical researchers, we deal with many different people (some with very large egos and very little diplomacy) to prepare the documentation we are expected to write. This seminar presents and practices some useful techniques in dealing with different contributors to and reviewers of documentation.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Writers with at least 8-10 months experience with regulatory documents.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<ol style="list-style-type: none"> <li>1) Familiarity with clinical trials and documentation.</li> <li>2) Independent medical writing experience.</li> <li>3) Experience of the preparation and review of clinical documentation.</li> <li>4)</li> </ol>
<p><b>Seminar content:</b></p>	<p>The seminar addresses the role of the medical writer within a clinical project team:</p> <ul style="list-style-type: none"> <li>• Team dynamics.</li> <li>• Interaction with people on a one-on-one basis.</li> <li>• Real life examples (good and bad).</li> <li>• Hands-on exercises.</li> </ul> <p>Discussion, demonstration and practice of using different approaches in different contexts aimed at minimizing interpersonal conflicts and overcoming those that occur.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Deal with and coordinate more confidently the social interactions needed within a clinical development team to produce the best clinical documentation.</li> </ul>

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**Seminar: S03 Project Management**

<b>Purpose:</b>	This seminar presents the project management skills needed by medical writers to ensure that input, review, and the final production of clinical documents all occur on schedule.
<b>Duration:</b>	Half day
<b>Intended Participants:</b>	Writers with at least 8-10 months experience with regulatory documents.
<b>Recommended experience and/or previous seminars required:</b>	<ol style="list-style-type: none"> <li>1) Independent medical writing experience.</li> <li>2) Experience of the preparation and review of clinical documentation.</li> </ol>
<b>Seminar content:</b>	<p>The seminar includes:</p> <ul style="list-style-type: none"> <li>• Considering the inputs and outputs necessary for a given documentation project.</li> <li>• Project scheduling.</li> <li>• Determining realistic deadlines and managing expectations of management and team members.</li> <li>• Project Monitoring, reporting and management.</li> <li>• Quality assurance and review.</li> <li>• Techniques for minimizing delay; what you can do in the case of late inputs to minimize later difficulties.</li> </ul> <p>The seminar uses the preparation of a typical “complex” document, the Investigator’s Brochure, as a case study in how to manage a project as a medical writer.</p>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Plan, organize and manage medical writing projects.</li> <li>• Set realistic deadlines and ensure quality delivery, on-time.</li> </ul>

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**Seminar: S04 Medical Writing Post-Submission and Leading to Approval**

<p><b>Purpose:</b></p>	<p>The objective of this seminar is to familiarise participants with the writing required for the post-submission review processes of the US (FDA) and European regulatory authorities (CHMP).</p> <p>While the Common Technical Document harmonises the structure of regulatory documents submitted to the European CHMP (Committee for Medicinal Products for Human Use) and the US FDA (Food and Drug Administration) for marketing approval, the review processes leading to the decision on whether to approve or not still differ markedly between the two authorities. In both cases, though, the demand for medical writing skills in the broadest sense (linguistic, scientific, organisational, and diplomatic) can be high.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Authors with at least 12 months of experience in clinical development.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<p>1) Minimum 12 months experience of clinical development.</p>
<p><b>Seminar content:</b></p>	<p>We draw on our personal experiences of working together for over four years in the post-submission phase of a drug development program, to illustrate the pivotal role medical writers can play in helping to optimise a sponsor's chances for obtaining a successful drug approval.</p>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Enhance the likelihood of speedy regulatory review by understanding the needs and expectations of regulatory authorities during their approval review process.</li> <li>• Understand likely areas of regulators concerns.</li> <li>• Answer reviewers' questions appropriately, speedily and concisely.</li> </ul>

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**Seminar: S05 Writing Successful Manuscripts**

<p><b>Purpose:</b></p>	<p>The seminar discusses the various things a medical writer should be aware of and thinking about to be able to write and submit a manuscript with the greatest chance for success.</p> <p>Manuscripts need to tell a story and the data included needs to be chosen to clearly support this story.</p>
<p><b>Duration:</b></p>	<p>Half day</p>
<p><b>Intended Participants:</b></p>	<p>Medical writers with at least 3 months of experience in basic medical writing or as part of a medical writing team.</p>
<p><b>Recommended experience and/or previous seminars required:</b></p>	<ol style="list-style-type: none"> <li>1) Minimum 3 months experience of medical writing.</li> <li>2) At least 2-3 foundation skills seminars (FS01-FS09) or equivalent.</li> </ol>
<p><b>Seminar content:</b></p>	<p>The seminar covers various aspects that are critical to planning and developing a manuscript:</p> <ul style="list-style-type: none"> <li>• Publication plans.</li> <li>• Understanding impact factors.</li> <li>• How to choose the right journal.</li> <li>• Journal requirements.</li> <li>• Publication guidelines and international practice: understanding the parts of a manuscript and what belongs in each part.</li> </ul>
<p><b>At the end participants will be able to:</b></p>	<ul style="list-style-type: none"> <li>• Assess the publication plan and how to choose the right journal for maximum impact.</li> <li>• Assess the message to be communicated and the best means of presentation to get this across quickly.</li> <li>• Produce Manuscripts and manage the process of review.</li> </ul>

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**Seminar: S06 Effective Poster Presentations**

<b>Purpose:</b>	<p>This seminar explores the fundamental concepts of how to prepare a poster to communicate to a broad audience.</p> <p>Posters must make a strong visual impact and catch the viewer's attention to communicate their message. It is a visual presentation of information and should be designed as such - not simply a written paper reproduced in poster format.</p>
<b>Duration:</b>	Half day
<b>Intended Participants:</b>	Scientists who want to improve the effectiveness of their poster presentations.
<b>Recommended experience and/or previous seminars required:</b>	None
<b>Seminar content:</b>	<p>The pre-seminar material, the seminar and the post-seminar assignment will introduce, actively explore and exercise:</p> <ul style="list-style-type: none"> <li>• Different design styles commonly used in scientific poster presentations.</li> <li>• The strengths and weaknesses of different styles.</li> <li>• The impact of good graphics and a simple, easy-to-grasp message that is central to a good poster.</li> <li>• The assessment of exactly who the poster and the writing are targeted at and making sure that the writer targets them.</li> </ul>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Assess the message to be communicated and the best means of presentation to get this across quickly and persuasively.</li> <li>• Produce Posters, know how to present them and manage the process of review.</li> </ul>

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**Seminar: S07 Preparing Effective Oral Communications**

<b>Purpose:</b>	When communicating in the spoken form, there is far more to consider than just the words. You need to capture and hold the attention of your audience. This workshop will explore how to tell a story about your data. We will also consider how to effectively use voice and physical presence to make presentations more dynamic.
<b>Duration:</b>	Half day
<b>Intended Participants:</b>	Scientists who want to improve the resonance of their oral presentations.
<b>Recommended experience and/or previous seminars required:</b>	None
<b>Seminar content:</b>	Participants will learn and develop fundamental ideas on how to structure a presentation so that it presents a logical flow of information and guides an audience through the messages to be communicated. The workshop will also introduce, actively explore and exercise how to use and control the voice and body to have the greatest impact.
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Understand how to structure an effective presentation.</li> <li>• Present scientific findings with more confidence.</li> </ul>

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**Seminar: S08 Medical Communication: Conference and Meeting Reporting**

<b>Purpose:</b>	When reporting on conferences and meetings it is important to choose the appropriate writing style to reach the target audience and to put in place logical building blocks to communicate the ‘take-home’ messages in a clear and convincing manner. This workshop will explore how to choose the right writing style in order to craft effective conference and meeting reports that reach the target audience. Additional points for covering conferences and meetings will be discussed.
<b>Duration:</b>	Half day
<b>Intended Participants:</b>	<ol style="list-style-type: none"> <li>1) Medical writers with experience in regulatory writing or who wish to explore other aspects of medical writing or have done some conference reporting and wish to improve their skills in this area.</li> <li>2) Communications writers with little or no experience of conference reporting.</li> </ol>
<b>Recommended experience and/or previous seminars required:</b>	New or experienced writers with limited experience of conference reporting.
<b>Seminar content:</b>	<p>Participants will learn writing in several styles: the compelling style used by journalists, the more formal styles used in reporting proceedings and the commercial styles appropriate for reporting the conclusions of advisory boards and in compiling competitor analyses. Practical aspects of covering meetings and conferences will also be discussed.</p> <p>Participants will be assigned both pre- and post-workshop assignments.</p>
<b>At the end participants will be able to:</b>	<ul style="list-style-type: none"> <li>• Craft effective conference reports, including clear ‘take-home messages’.</li> <li>• Choose an appropriate writing style; taking into account the target audience.</li> <li>• Have an idea of the approach to be taken before starting, and when writing up a conference or meeting report.</li> </ul>