

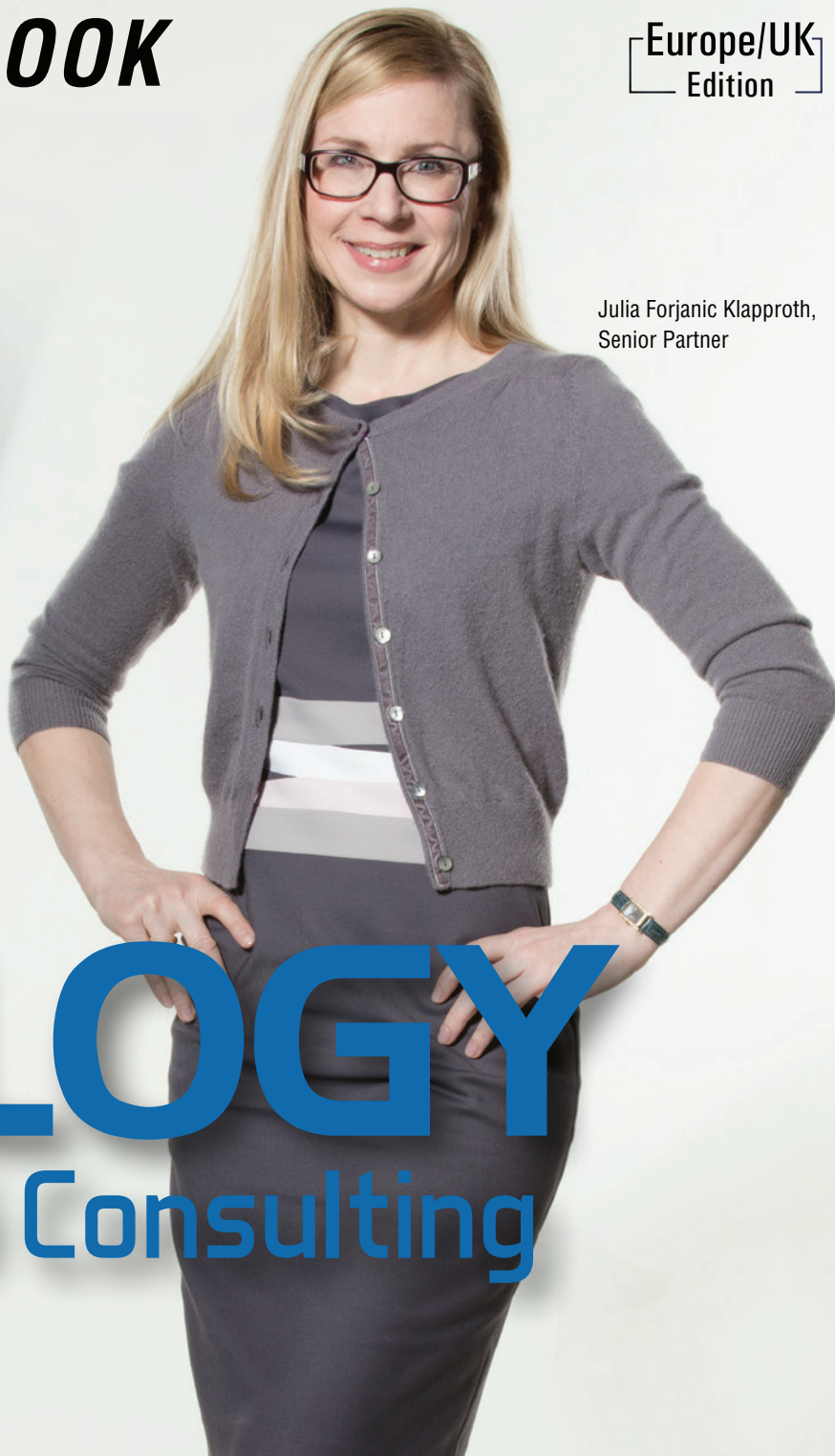
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TECH OUTLOOK

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CLINICAL TRIAL
MANAGEMENT
EDITION



Julia Forjanic Klapproth,
Senior Partner

**Quality-
Driven
Medical
Writing**

TRILOGY

Writing & Consulting



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Quality-Driven Medical Writing

By Stacey Smith

For years, the clinical drug development industry has been waging war against the surging drug development costs and tediously long processes. More efficient decision making during drug development would be a crucial differentiator that the industry needs to win this battle. To achieve this, drug development companies must bring together a deep understanding of core competencies with equal input from all the stakeholders at each decision making touchpoint. One of the key stakeholders with an instrumental role to play in this process is the medical writer. Conveying the intended message of a clinical document clearly, and in a timely manner, is critical to the success of clinical program – whether communicating effectively to study site staff and investigators, patients, or the regulators. This calls for a specialist medical writing team.

Given how the success of clinical development programs, and drug approval itself, depends on the readability and reviewer-friendliness of the clinical documentation, a medical writer has the potential to optimize the documentation process by providing a clear presentation of clinical study results. From designing the clinical study protocol through to writing the submission

dossiers, an experienced medical writer can help drug development teams to evaluate the kind of data that needs to be collected and how that data will converge to support the intended claims of a product.

The evolution of the medical writer into a more valued cog in the machine of drug development has paralleled the increasing volume of documentation needed in drug development processes to comply with stringent clinical study regulations. The growing demand for clinical documentation has also set new standards of speed in content preparation for modern-day medical writers where everything from time to database closure of a study, time to final clinical study report, and time spent writing dossiers is oftentimes unreasonably expedited. In the pursuit of meeting these condensed timelines, it is not unusual that the quality of the medical writing is compromised as teams are given less and less time to craft the documents.

Trilogy Writing & Consulting is breaking away from this norm and revolutionizing medical writing. Backed by a culture of producing quality content and not being driven purely by profit, Trilogy is a medical writing consultancy that works proactively with its clients in the drug development space to plan, coordinate, and prepare



At the core of our medical writing is ensuring quality clinical documentation by fostering a good work-life balance among the writers

Julia Forjanic Klapproth,
Senior Partner





Solution
Marketing
Analysis
Ideas
Success
Management



clinical documentation that not only meets the client timelines but also communicates the complexity of the material clearly and concisely.

Established in 2002, Trilogy started out with three people. Today the company employs more than 50 writers across three offices and the company has evolved considerably in the last 18 years. The company's staff consists of a unique blend of seasoned and qualified professionals paired with a multitude of new writers, where Trilogy provides its budding writers with appropriate training and tools from scratch. In speaking with Julia Forjanic Klapproth, Senior Partner at Trilogy Writing & Consulting, she explains, "This knowledge sharing of the expertise from experienced writers to developing writers is time intensive, which accounts for the gradual and organic growth of Trilogy as an organization, but yields excellent results. With optimum quality services at the core of everything we do, we are today positioned as a boutique medical writing company."



Julia Forjanic Klapproth,
Senior Partner

Through its proactive approach, the company delivers exceptional expertise and readability that reduces the time for review and approval. Citing a case study of a recent client engagement, Julia highlights the wealth of experience and the proactive approach that Trilogy brings to its clients. According to Julia, one of Trilogy's clients was uncertain whether or not to write a separate ISS in addition to Module 274 as part of their submission to the FDA. Trilogy stepped in to simplify their decision-making by assuring them that submitting only 1 safety summary (i.e. either a Module 2.7.4 or an ISS) is an industry-standard practice and saves significant time, resources, and

stress for the team. Trilogy informed the client that such an approach is also quite preferable for FDA reviewers as they will have only one document to review instead of two covering essentially the same information. Bringing such expertise and advice to its clients, Trilogy helps them do their dossiers in less time, while ensuring that all the regulatory requirements are met and that the documents will enhance review by making the messaging clear and navigation easy. In this way, the company sees itself as partners with its clients on a mission to get products to market faster by aiding review and approval.

As a step towards shortening the time to prepare clinical documentation, Trilogy is also in the process of developing its proprietary AI tool. This is designed to pull together data from the source outputs and generate an initial draft of a study report that the medical writer and clinical team can then craft into a well-rounded story. The tool focuses on doing what technology does well – pattern recognition and data culling – so that the team can focus on what they do well – interpretation of what it all means. The AI tool will bring time savings not only by pulling together the information rapidly (reducing generation of an initial draft from days to minutes) but also by the reduction in the need for quality control of the data in the document, as this will no longer be generated by manual entry. Ultimately it will help drug development companies bring together the results of studies within a shorter time period with greater accuracy and will help ensure teams do not overlook any potential signals in the data, as these will be flagged to the team by the tool.



A major part of our approach is that we put a minimum of two writers on every document and encourage a collaborative team spirit in the whole process of documentation


Finding Value in Medical Writers

According to Julia, medical writers need to be working in a conducive environment in order to perform to their best. However, a lot of modern companies are profit-driven and accept every opportunity that comes their way, irrespective of available human and technical resources, and consequentially end up treating their medical writers as commodities. At many companies, writers are overburdened with too large workloads and long working hours. Trilogy aims to eliminate this culture in medical writing by promoting its virtue of being quality-driven over profit-driven. “A major part of our approach is that we put a minimum of two writers on every document and encourage a collaborative team spirit in the whole process of documentation,” says Julia. By assigning multiple writers to work jointly as a team on a single document we are often able, through “parallel processing” (i.e. different sections are assigned to different writers to prepare in parallel, with oversight remaining with the Lead Writer to ensure consistency), to not only shrink the

timescales of production achieved by traditional medical writing methods but also better manage the stress of the writers during crunch periods.

“At the core of our medical writing philosophy is ensuring quality clinical documentation by fostering a good work-life balance among the writers. Through our approach, we allow writers to progress in a diverse environment with the right level of challenges that enable them to grow,” says Julia. “We are also selective about the companies that we engage with, giving preference to relationships based on mutual respect, as we believe this is a cornerstone of a well-functioning vendor and client relationship, and even more so, it is crucial to making sure that our writers are enjoying what they are doing and are performing to their best,” adds Julia.

The Journey Beyond the Horizon

Ultimately, Trilogy’s aim is for the drug development industry to recognize the importance of training their medical writers formally and efficiently and the value added of having well-trained writers prepare documents. With their focus on training and developments like the AI tool, Trilogy aspires to raise the bar of the current global stature of medical writing and take it to the next level. Julia says, “We see our company evolving as a thought leader in this area and hope to make an impact in driving the training and grooming of best-in-class medical writers industry-wide.” From a geographical standpoint, apart from its HQ in Frankfurt, Germany, Trilogy has offices in North America and the UK, with its US base located in North Carolina. In the coming days, the company plans to throw the net across North America in its search for experienced writers and further expand its presence countrywide. Today, powered by the leadership of Julia and the other Senior Partners, and the collective expertise of its seasoned writers, Trilogy is at the forefront of changing the face of modern medical writing. 

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TECH OUTLOOK

Clinical Trial Management Edition

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Top 10 Clinical Trial Management Consulting/ Service Companies in Europe - 2019

For several decades, researchers have emphasised the need for large, randomised, and controlled trials to bring out the highest level of evidence that would help them come to an inference for their clinical trials. Most often than not, many trails fail to deliver the desired result due to the lack of a practical, structured, and business-like approach to trail management. Meanwhile, clinical trials are intertwined with potential risks in communications and management, as various stakeholders are involved in performing the trials. At this critical juncture, pharmaceutical centres must have an inherent responsibility and obligation to conduct and manage clinical trials while preserving a high level of quality. To mitigate this impediment healthcare professionals are seeking for eminent clinical trail management service

providers who can guide them beyond the advisory level and bring in the optimal solutions.

To help pharmaceutical organisations partner with the best service providers in the industry, Pharma Tech Outlook has compiled a list of top 10 clinical trial management services in Europe/UK. Equipped with innovative technological capabilities and robust offerings, the enlisted companies are constantly proving their mettle in the pharmaceutical sector. To further substantiate the technological advancement in clinical trial management, CIOs working in the industry have penned their insights about new innovations, industrial happenings, and their advice to the aspiring CIOs seeking for it.

We present to you Pharma Tech Outlook's "Top Clinical Trial Management Service in Europe/UK."

Trilogy Writing & Consulting

recognized by  magazine as

Top 10
CLINICAL TRIAL
MANAGEMENT
CONSULTING/SERVICE
COMPANIES IN EUROPE - 2019

*The annual listing of 10 companies that are at the forefront of providing
Clinical Trial Management consulting services
and impacting the marketplace*

Company:

Trilogy Writing & Consulting

Description:

Specializes in clinical regulatory documents, especially CTD submission dossiers, post-marketing documents, safety documents, and writing for patients

Key Person:

Senior Partners:
Julia Forjanic Klaproth,
Douglas Fiebig,
Barry Drees,
Lisa Chamberlain James

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trilogywriting.com