

# A medical writing primer for oncology dossiers

**Julia Forjanic Klapproth, Maurice Löwens**  
Trilogy Writing & Consulting  
Frankfurt am Main, Germany

## Correspondence to:

Julia Forjanic Klapproth  
julia@trilogywriting.com

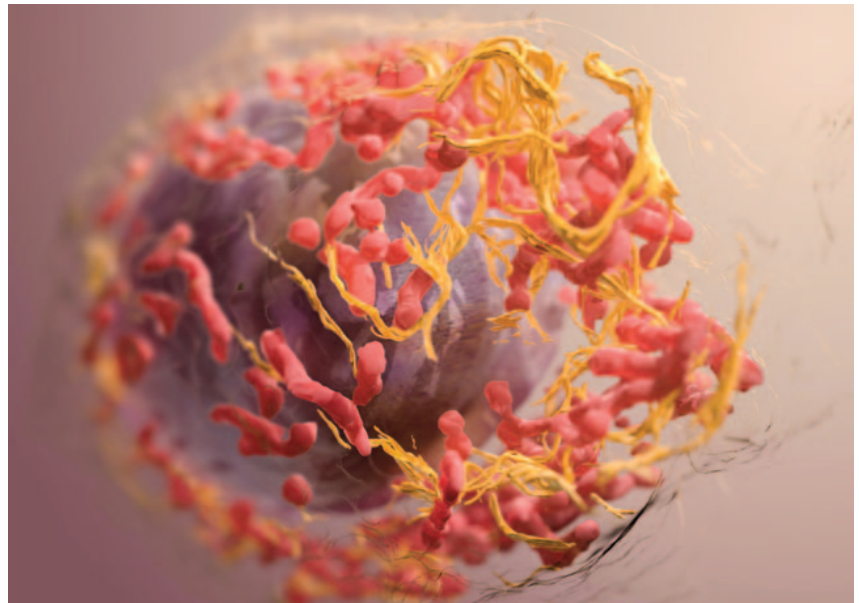
## Abstract

Oncology is one of the most common areas of drug development in the pharmaceutical industry. As a medical writer, it is important to be aware of the unique aspects of oncology studies and have some understanding of the principles underlying cancer therapies. This article outlines a number of key hurdles faced with oncology studies and dossiers and guides medical writers through these so they can bring meaningful advice to their dossier team and prepare a high-quality submission dossier.

In 2020, the majority of new drugs approved by the FDA were for cancer treatment.<sup>1,2</sup> Existing cancer drugs are also regularly approved for multiple indications, which adds to the workload for each drug.<sup>2</sup> The data needed to prepare the submissions to get these drugs approved come from large numbers of oncology studies taking place all over the world. This means, as a medical writer, you will likely be involved in writing documents for an oncology programme at some point in your career and it is important to be aware of the unique aspects of oncology studies and have some understanding of the principles underlying cancer therapies.

## Oncology-specific challenges for medical writers

Coming to terms with the terminology and acronyms as well as the oncology-specific efficacy endpoints (progression-free survival, overall response rate, duration of response) can be challenging when you first get into the oncology arena. Cancer is a disease that is frequently treated over the long term, and even when the



cancer has been eliminated, follow-up continues for years. As a result, the endpoints to assess efficacy tend to look at the effect over time and its endurance, not just a static assessment of whether the disease is cured, as in many other therapeutic areas. The challenges associated with this in the context of submission dossiers arise from the fact that there are often multiple interim study reports, in addition to the final Clinical Study Report, and multiple data cuts over time (sometimes with different data cuts across multiple studies), which can be tricky to explain to the reader of a submission.

Cancer therapy is also a very dynamic area with developments in biotechnology rapidly shifting the approach to treatment. The medical dogma in many cancer types can shift swiftly, which means that the scientific rationale, currently available treatments, and medical-need descriptions often need to be updated frequently – sometimes changing considerably, even within a 12-month period, as new treatment options change the therapeutic landscape.

## How to support oncology dossier teams

As medical writers, our role is to collaborate with the clinical experts to understand their vision for the treatment being studied and to crystallise the messaging from the clinical programme. We need to work with them to know where current changes in the medical opinion might need to be

reflected in the medical-need discussion and to understand how the product under assessment needs to be positioned in the overall picture of available therapies. Frequently, because the clinical experts are often deeply involved in the research going on in their area, we also need to help get them to look at the big picture for the purpose of registration. It is important that the regulatory documents we write stay focused on what is needed to get regulatory approval of the target product profile (TPP) and not get bogged down and off-target in academic questions (that can be very interesting but should be saved for publications).

To be able to do this effectively, it is essential that submission teams have a clear and well developed TPP from the start of a clinical development programme. Ideally, the programme should be reverse engineered to specifically collect the data that will be needed to support the intended claims of the TPP. At the latest, it should be ready by the time writing on a submission dossier begins. Without the TPP, it can be challenging to know what aspects to focus on in the Module 2 summaries. If written in parallel, it often gets in the way of writing the dossier as the team chases a moving target. Having the TPP ready and agreed on well in advance gives the team clarity on what issues to focus on throughout the clinical programme, in general, and when writing the Module 2 summaries, in particular.

### Common hurdles and how to handle them

During an oncology clinical programme, it is not uncommon to have multiple dose modifications as the investigators adapt to manage adverse events and slowly home in on the optimal dose regimen. Early studies can have different dosing regimens than later studies. As a result, treatment groups can be very fragmented, making it very difficult to interpret the data, particularly in a pooled dataset, because the data cannot be easily compared across different doses. Changes in dosing can also mean that the proposed dose has less exposure time than earlier doses. These problems affect the interpretation of both efficacy and safety and need to be considered carefully when planning how to present the data in the dossier.

Another hurdle that teams often grapple with when writing oncology dossiers is how to handle adverse events of special interest (AESIs). Due to the different organs affected by different cancers, there is often little consistency in the AESIs collected in different studies. This presents a challenge when summarising them across studies in Module 2.7.4. Do you try to find a consistent grouping of these across studies in different cancer types, or do you just present AESIs from the pivotal trial? In oncology, the AESIs will be driven by the risk factors from the underlying disease (cancer type) and in a large dossier, you will need to find a way to bring some very diverse safety data together. This should be thought

about as early as possible when the team begins to plan for the dossier, and it certainly needs to be discussed in the statistical analysis plan (SAP) for the safety summaries.

### Useful things to consider

Kaplan-Meier plots are widely used in oncology programmes for the depiction of overall survival as well as the time to onset and time to resolution of adverse events. These plots can be very useful in visualising how much of a difference there is for the duration of survival in patients treated with the drug under assessment vs. other treatment options. Similarly, in the context of adverse events, Kaplan-Meier plots can help make clear the periods of risk for drug-related events. It is helpful for medical writers to understand how Kaplan-Meier plots work, so they can provide useful context when writing about these.

Something else to keep in mind when planning for and writing oncology dossiers is whether there is a likelihood of submitting in other regions (e.g., Japan). If so, have a discussion with the colleagues from those other regions while developing the SAPs for the efficacy and safety summaries to be sure that all analyses will be planned as required or expected by their local agencies. There is nothing more frustrating than thinking the dossier is fit-for-purpose for a global submission, only to find out that you need additional analyses to be run and incorporated into the files.

While subject matter experts are focused on their particular area of expertise, a medical writer is far enough away from the minute details to be able to add value and guidance to ensure the documents stay focused and fit for purpose.

### Conclusion

Overall, an experienced medical writer can bring meaningful advice and guidance to the dossier team. While subject-matter experts are focused on their particular area of expertise, a medical writer is far enough away from the minute details to be able to add value and guidance to ensure the documents stay focused and fit for purpose. Medical writers often come to the project with a fresh pair of eyes and they can ask the naïve questions that the team may have completely overlooked. With a strong regulatory lead who has a good vision of the target and clinical experts who understand the therapeutic benefits to be gained, a strong medical writer rounds out a dossier team by advising on how to present the information with clarity that will direct agency reviewers to what they are looking for and aid the approval process.

### Disclosures and conflicts of interest

The author, Julia Forjanic Klapproth, owns Trilogy Writing & Consulting, a company specialised in providing regulatory medical writing. Maurice Löwens is employed by Trilogy Writing & Consulting. The authors declare no conflicts of interest.

### References

1. New oncology drug approvals in 2020. *Clinical Oncology News*. 2020 [cited 2021 Dec 9]. Available from: <https://www.clinicaloncology.com/FDA-Watch/Article/12-20/New-Oncology-Drug-Approvals-in-2020/61464>
2. In the pipeline: Specialty drugs to watch in 2021. 2021 [cited 2021 Dec 9]. Available from: <https://blog.navitus.com/specialty-pipeline-2021>

### Author information

**Julia Forjanic Klapproth, PhD** started working as a medical writer in 1997, and she is passionate about the value of good medical writers. In 2002, she co-founded Trilogy Writing & Consulting, a company specialised in providing regulatory medical writing. Julia has been President of the European Medical Writers Association (EMWA) twice (2001-2002, 2007-2009).



**Maurice Löwens** has over 13 years experience as a medical writer, having worked on numerous types of clinical regulatory documents. In his current role as a Senior Medical Writing Manager at Trilogy Writing & Consulting, he leads teams of writers on a wide variety of regulatory writing projects.