Morula Health

IMMUNO-ONCOLOGY

FDA-aligned CSR and Narrative Writing Support for Complex Immuno-Oncology Programs

OVERVIEW

Our recent project with this biotech focused on the preparation of a complex clinical study report (CSR) for a multi-part expansion phase study in various solid tumors and patient safety narratives to support their US clinical trials. This project involved writers who were confident in writing documents for FDA guidelines and expertise with managing large, complex clinical datasets, ensuring consistency between the CSR and supporting documents, and developing concise safety narratives that accurately captured patient-level events while maintaining scientific and regulatory precision.

CHALLENGE

The scope included preparation of a CSR and a large set of patient safety narratives for a Phase 1/2a oncology trial intended for FDA submission. The CSR required integration of data across multiple study parts within an adaptive design, demanding clear structuring and consistency. Alignment with ICH and FDA guidelines required strong regulatory judgement alongside deep oncology expertise.

The biotech required:

- Writers with deep solid-tumor oncology expertise to interpret a complex study design and specialized terminology
- A structured approach to manage over 120 individual patient narratives, each with a unique clinical course
- Development of a clear, consistent safety narrative template to address data variability and inconsistencies
- Strong clinical judgement to liaise with the clinical team to identify and appropriately present clinically significant adverse events
- Operational ownership of document management, including version control and tracking of parallel review cycles

ABSTRACT

A UK-based biotech engaged Morula Health to support the advancement of its oncology pipeline. Initially working with a freelance medical writer and CRO, they valued the flexibility and therapeutic expertise provided. However, as their immuno-oncology program expanded, they found it difficult to scale delivery across multiple documents in parallel. This highlighted the need for a medical writing service provider. They started working with Morula Health because of our FDA and oncology expertise and ability to be flexible partner who could embed within their team, scale with ongoing studies, and provide continuity, reliability, and operational oversight, what we describe as a "best of both worlds" approach.

Our first collaboration was an Investigator's Brochure (IB) update, after which we became their trusted medical writing partner, supporting a broad range of clinical and regulatory documents across their programs.

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WHY BIOTECHS CHOOSE MORULA HEALTH

- ✔ Deep, narrative-specific regulatory expertise
- ✔ Strategic leadership that reduces risk and internal burden
- ✔ Efficient, high-quality delivery with built-in quality control

SOLUTION

Morula Health assembled a dedicated oncology writing team and integrated directly with the client's clinical and regulatory functions, taking ownership of both the writing and the delivery process.
Our approach included:

- ★ Templates and data source rules agreed before writing began, removing ambiguity from the narrative development process
- ★ A batch-based delivery workflow with small early batches to ensure alignment on content and structure, reduce rework, and improve efficiency
- ★ Assignment of highly experienced writers with expertise in solid tumor and immuno-oncology, CSRs, narratives, and FDA requirements
- ★ One writer leading both the CSR and safety narratives, driving consistency and cohesive deliverables
- ★ SharePoint-based document management with separate areas for writers and reviewers, managed by the Morula Health project management team
- ★ Proactive communication and review coordination, reducing the administrative burden on the client throughout and structured review periods to manage limited availability and timelines

OUTCOME

The client valued the continuity of the writing team, the depth of oncology experience, and the operational support. Feedback highlighted the team's flexibility, their ability to adapt to changing program needs, and the benefit of working with a partner that functioned as an embedded medical writing service. Over time, Morula Health became the client's primary medical writing partner, supporting multiple Investigator's Brochure updates over several years, delivering two CSRs, contributing to protocol development, and supporting scientific advice meetings. The same team of Medical Writers worked across the partnership, ensuring consistency and deep familiarity with the program and team. With the client's clinical trials running in the US for the first time, Morula Health's experience of FDA requirements ensured all documents were written and structured to meet FDA expectations, supporting the team's expansion into the US market without adding regulatory risk.

Get in touch to discuss how our experienced team and Medical Writers can support you.
Visit our website to learn more: www.morulahealth.com