**Role of a Medical Writer in a CRO**

Contract Research Organisations, otherwise called as CROs, provide contract-based services for Pharmaceuticals, Biotechnology and Medical devices companies at various stages of their drug development. The activities that a CRO undertakes include preclinical studies, clinical research and clinical trials, regulatory activities, and pharmacovigilance. CROs have technical competency and expertise in performing these activities. The company that outsources these overwhelming activities to a CRO is called a sponsor or client company. The CROs add value to the sponsor companies by reducing the time required to bring the drug into the market.

CRO’s usually hire highly qualified personnel holding life science related degrees. Among the various staff, [medical writers](https://onlinemedicalwriting.com/blog/2019/05/23/what-is-medical-writing/) play a crucial role in a CRO in handling the variety of documents involved in the drug development and its reporting. A medical writer who understands the drug or device development process and regulatory activities is an important asset for the team. The key function of a medical writer is to develop accurate, clear, and compliant documents as per the project and the regulatory requirements.

A medical writer in a CRO is required to create and maintain a [wide spectrum of documents](https://onlinemedicalwriting.com/blog/2019/05/23/what-are-the-different-types-of-medical-writing-healthcare-communication/), few of them include:

**Protocol writing**: It is a detailed document that demonstrates the guidelines for conducting the clinical trial, it contains the study objectives, design, methods, assessments, and statistical data.

**Investigator’s brochure**: It is an updated document that outlines the entire clinical trial process to the investigator.

**Clinical Study Reports**: Popularly called as CSRs are detailed documents that describe the methodology followed and the results obtained in a clinical trial.

**Informed consent forms**: The document reflects the study participant’ agreement to be a part of the study, and contains the purpose of the research and his/her role, which is usually explained to them before seeking their willingness.

**Efficacy or Safety summaries:** These crucial documents are official records of adverse reactions occurring due to the investigational drug during the clinical trial phase.

**New Drug Applications (NDA)**: NDA is submitted by a sponsor company to the FDA for approval to sell and market the drug. The NDA includes detailed information about safety, efficacy, benefits vs risks, and package inserts.

**Patient Narratives**: These documents are summaries of adverse events experienced by patients during the clinical trial. Narrative writings involve patient profiles, review of data sources, and identification of events which require a narrative.

**Package Inserts**: These are documents included in the package of a medication and provide information about that drug and its use.

**Manuscripts** – This document is a publication-ready account of the important findings of the study. The manuscript is published in journals to let the peers know about the study and its results. Clinical research manuscripts usually include: Introduction, Methods, Results, and Discussion (IMRAD).

Medical writers in CRO collaborates with biostatisticians, medical specialists, scientific experts and sponsors to develop high quality documents abiding to the ICH GCP requirements. Here are few considerations to be hired as a medical writer in a CRO:

* Background – Lifesciences degree like medicine, pharmacy, biotechnology and chemistry are usually preferred.
* Experience – Previous experience or knowledge about clinical trials, regulatory affairs or pharmacovigilance can be an advantage.
* Certification – A [certification program in medical writing](http://www.onlinemedicalwriting.com/) may provide necessary exposure to the various clinical research and regulatory documents.
* Soft skills – Apart from good writing skills. a medical writer must have good oral communications and project management skills.

CROs usually aim to proliferate the markets with their newly launched products, and preparing these communication materials becomes crucial for creating the identity for the products. [Medical writers](https://onlinemedicalwriting.com/blog/2019/05/23/who-hires-a-medical-writer/) perform a key role in enabling this process. If you are the one who is looking out for an adventurous profession and are good in juggling multiple works, medical writing is the profession you must explore!