# TMF Support Analyst

**Missions/Goals**

* To provide internal and external teams with outstanding TMF operational expertise and ensure deliverables with quality, on time, and cost-effective with measurable services.
* To develop strong values and foster innovations in TMF process.
* To continuously improve performance and productivity (ensure high skill level), and provide operational excellence through best practices and lesson learned.

# Role Description

Position Title: Trial Master File (TMF) Support Analyst I/ Support Analyst II/Senior Support Analyst

Reports to: President and CEO/Vice President of Clinical Operations/Project Leader/Project Manager/TMF Support Analyst Manager

Location: Remote/Clients Office/Raleigh,NC

# Position Purpose

The Trial Master File (TMF) Support Analyst is the Quality Control Expert and will ensure TMF and documents accuracy and completeness. The clinical trial documentation must be consistent with the Trial Master File Specifications, submission/inspection readiness criteria and comply with LMKs (or clients) SOPs and regulatory requirements. The TMF Support Analyst is to serve as single point of contact to the TMF Project Manager or equivalent to ensure a complete and accurate TMF through documentation quality and consistency across clinical trials and programs. The TMF Support Analyst may also serve as a subject matter expert in Theralign commissioned projects. There are three tiers of TMF Support Analysts reflecting increasing experience and responsibility with increasing level.

# Primary Responsibilities

* Perform TMF and Quality Control (QC) and remediation across functional lines.
* Scan and index documentation into the eTMF.
* Support teams during inspection or audits.
* Ensures documents maintained in the TMF are appropriate and the content of those documents are accurate, complete and consistent with LMKs (or clients) SOPs and regulatory requirements.
* To provide project teams with outstanding trial and data management expertise/resources, and ensure deliverables with quality, on time, and cost-effective with measurable services.
* To develop strong values and foster innovations in TMF implementation, maintenance and good documentation practices.
* To continuously improve performance and productivity (ensure high skill level and performance of staff), and provide operational excellence through best practices and lesson learned.
* Ability to work in an international environment with internal and/or external partners (CROs, etc.).
* Strong English skills (verbal and written if English is the second language).
* Ability to adapt and be flexible to change and managing internal and external impediments.

# Training and Education Preferred

Candidates for the position should have the following levels of experience: Minimum of Bachelor’s Degree or equivalent required. Clinical Documentation Management and industry experience to have a thorough understanding of the processes associated with conducting a clinical trials and document management operations.

* 1-2 years of Clinical Research Experience or professional equivalent
* 1-2 years of Document QC experience or professional equivalent

LMK Clinical Research Consulting, LLC is an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, or any other characteristic protected by law.