LMK Clinical Research Consulting is pleased to partner with Verdure Bay to present a webinar: "TMF QC: The Light at the End of the Tunnel" on Wednesday, 15 July 2015, 1:30 - 3:30 pm (EDT).

At LMK, we believe that there are three types of TMF QC: Prospective (ongoing studies), Retrospective (completed studies) and Oversight (studies that are outsourced). The webinar will focus on creating a **Prospective TMF QC process**.

A prospective TMF QC is an ongoing quality control check of the content filed in the TMF that is performed throughout the duration of the study. The prospective QC should be performed at defined time intervals (eg, every 60 days). The review can consistent of the full TMF or the essential documents (as defined by ICH). If possible, any issues should be remediated as they are identified.

Highlighted below are five key elements for creating a sustainable prospective TMF QC process—one that can be easily followed by all Functional Lines. The webinar will focus on the elements listed below:

If you would like to attend the webinar, please visit the enclosed link to register:

http://www.microrite.com/training/trial-master-file-quality-control-the-light-at-the-end-of-the-tunnel

Key Element	Consideration
Timing	An understanding of the study and company requirements is important in ensuring timely document collection and subsequent QC. For example: • Understand the life cycle of different documents collected from different Functional Lines/Study Team members – Typically, documents from *Clinical Operations* (eg, monitoring, trial management, etc) are uploaded into the TMF at a much faster rate and checks on these documents should be performed at closer intervals than documents from *Regulatory Affairs* (eg, Regulatory Authority Submissions and Approvals) these checks may be performed further apart. • Standard Operating Procedures – Know which documents should be collected and when. • Study Phase – Impacts the document collection process and schedule (eg, single country/single center Phase I studies are typically short and there will not have documents collected for a long period of time compared to large Phase III studies which may have documents collected over a span of many years).
Tool	Most companies *assume* that an Excel spreadsheet is the easiest way to document the QC results. Yes, a spreadsheet can be set up quickly (columns and rows) and can be filtered to see certain things, but what about the large oncology studies that are ongoing for years? The spreadsheet will be hundreds of thousands of rows long! Excel also has a row limit, and the tracker will spill over to multiple tabs (imagine trying to filter that!). Instead, try using an **online tool** like SharePoint—multiple people can access it at same time, and it is incredibly user-friendly.

True Review	An **in-depth QC** is not an inventory of what is present or missing in the TMF. In order to complete an in-depth review of the documentation present, it is *essential* to review the study's **reference documents** (eg, protocol, Investigators' Brochure, etc.) to understand the study, inclusion criteria, study drug, etc. Can you imagine saying to a Regulatory Inspector, "*Apologies, I am not sure how many versions of the Data Management Plan are supposed to be present*." Therefore, it is not acceptable during a QC.
Standardization	What constitutes a **pass or a fail**? Does everyone understand the criteria? It is very important to document the criteria for passing a document and for failing a document. When creating TMF QC standardization, understand the type of documents that are collected and subsequently reviewed. Performing QC on the *Form FDA 1572* is not the same check that will be performed on a *Statistical Analysis Plan.*
Metrics	Metrics—everyone's favorite word. TMF QC helps to evaluate the overall health of the TMF, but what are the items that need to be measured to determine the health of a TMF? The measurement can be as simple as counting the total number of document types, the number of fails, and then calculating the *fail* rate. A more sophisticated system can be implemented where the fail rate can be broken down by Functional Line, document type, or even milestone! The possibilities are endless when the metrics are set up correctly.