KLIFO Clinical Vault eTMF solution hosted by Veeva

A flexible and compliant solution for companies not ready to implement and maintain their own eTMF system

The requirements for content, management and archiving of a Trial Master File (TMF) are constantly increasing.

As sponsor, you must ensure that data in the TMF complies with the ALCOA++ principles, i.e. data must be attributable, legible, contemporaneous, original, and accurate as well as complete, consistent, enduring, available and traceable. Content should suffice to reconstruct the activities undertaken in the trial conduct.

Various eTMF options are available
Currently, various eTMF options of different quality, complexity, user-friendliness and price points are available in the market. Therefore, deciding on a solution that addresses current and future needs can be difficult.

The Veeva Vault eTMF is a well-known and widely used cloud-based, GxP-validated system designed to support the needs of eTMF maintenance, using the Reference Model and Expected Document Lists to control and track the eTMF documents properly.

KLIFO Clinical Vault hosting solution hosted by Veeva
KLIFO's Veeva Vault eTMF is a hosted solution that is ready to use and suitable for companies that are not yet prepared to implement and maintain their own eTMF system. It offers:

- A solution for management and oversight of documents depending on sponsor need
- Access to the system for internal and external stakeholders
- Support to content migration from/to another Veeva Vault or repository
- A fully GxP and 21 CFR Part 11 compliant solution

KLIFO Clinical Vault hosting solution supports:

- **Full eTMF for active studies**
  Setup and hosting of full eTMF for active studies, updated by sponsor, KLIFO or CRO
- **eTMF for sponsor oversight documents**
  Setup and hosting of eTMF for sponsor oversight documents for active studies, updated by sponsor or KLIFO
- **eTMF Archive**
  Long-term archival of finalised trials, including transfer of files from one or several locations, vendors and repositories into Clinical Vault.

KLIFO Clinical Vault is a highly flexible eTMF solution hosted in Veeva Vault and can be customised to your needs and internal resources.

Easy to implement and maintain
KLIFO ensures proper study setup and takes care of system maintenance, including handling of Veeva's general releases. KLIFO also manages user administration. Technical support, quick guides and best practice guidance for document management are available.

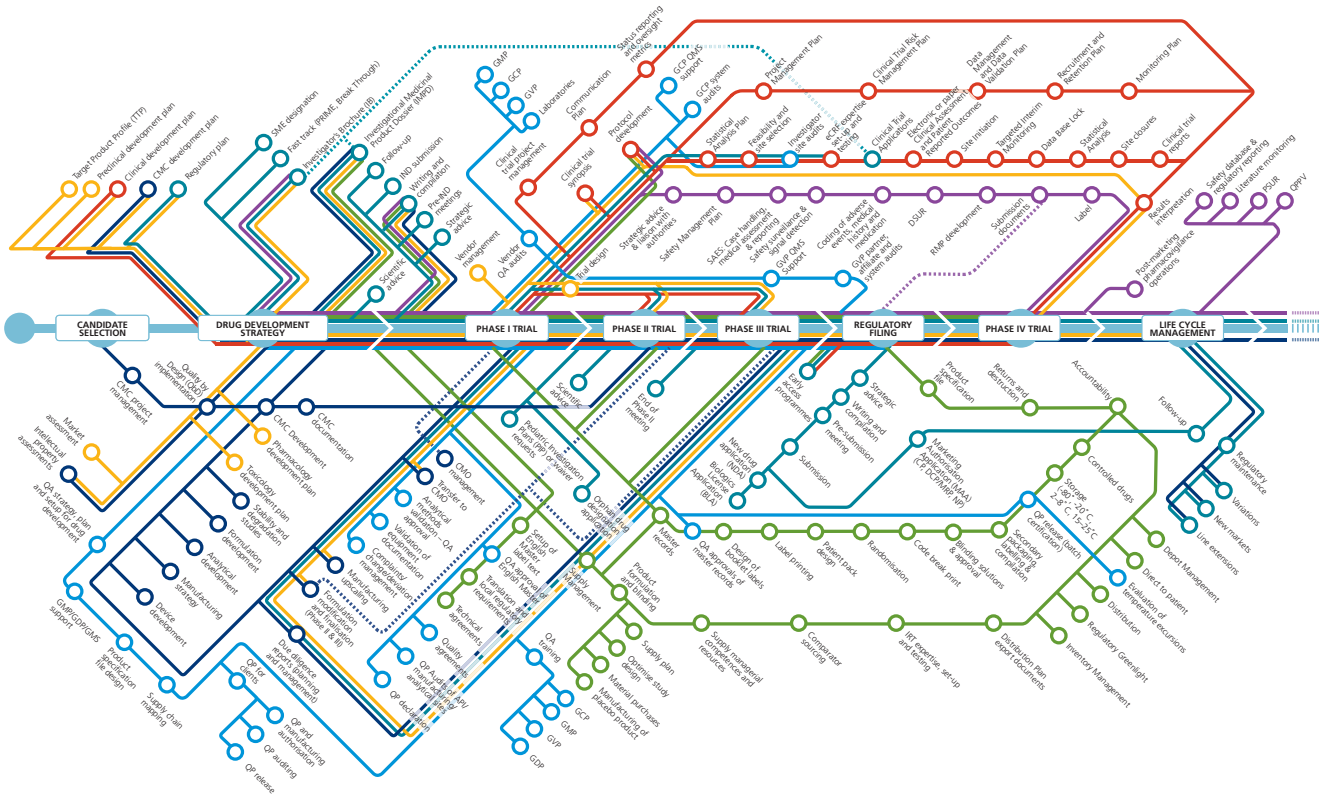
Electronic Document Management System
KLIFO has designed a user-friendly and compliant EDMS solution within Veeva Vault specifically for the biotech industry. The EDMS solution can be added to the eTMF solution or provided separately.

KLIFO is an integrated drug development consultancy

KLIFO is an integrated North-European drug development consultancy with significant experience in partnering with pharmaceutical and biotech companies.

We offer end to end solutions across all drug development areas, incl. strategic project management, regulatory affairs, clinical development and operations, clinical trial supply, QA, CMC development, non-clinical development and pharmacovigilance.

We provide strategic advice as well as operational support in all these areas.



To learn more about the KLIFO Clinical Vault, hosted by Veeva, please contact

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