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eTMF SERVICES

HOW SUBMISSION READY IS YOUR STUDY?

CHALLENGE
32% of FDA submissions have critical data conformance issues. Clearing up these issues delays market approval for vital drugs. You need to understand your studies holistically so that you know you're inspection- and audit-ready.

SOLUTION
We use Veeva Vault, the market's leading eTMF software, and augment those capacities with our best-in-classes processes and procedures. You know that your studies are backed by the best.

OUR OFFER

CHOOSE THE OFFER THAT WORKS BEST FOR YOU

FULL-SERVICE SUITE INCLUDING eTMF
STAND-ALONE ETMF SERVICES
PTMF TO ETMF CONVERSION

DEDICATED TEAM WORKING WITH SPONSOR'S VAULT
INSPECTION READINESS CHECKS, EXTRA CHECKS & QUALITY REVIEWS OF EXISTING eTMFS

#01 Dedicated central reviewer team

#02 Trained project leaders, CRAs & CTAs in multiple countries

#03 Processes & technology such as Veeva Snap to drive efficiency & eliminate errors

#04 Metrics & markers to detect errors & gaps in eTMF on an ongoing basis

#05 Final review with eTMF specialists to double check for quality

eTMF WORKFLOW

FULL-SERVICE SUITE INCLUDING eTMF

STEP 1

TMF PLAN
· PM creates the TMF plan with the support of TMF specialist
· Ensures team is trained on specific TMF Plan

STEP 2

DOCUMENT UPLOAD
· Document owner collects and/or generates a TMF document
· Accountable for First Time Quality (FTQ), Timeliness and Completeness

STEP 3

QUALITY REVIEW
· Independent reviewer (FTQ Reviewer) reviews documents based on list of quality expectations as per TMF plan at specific intervals
· Generates Quality Issues (QIs)
· PM FUPs with document owners for the resolution of QI per timelines

STEP 4

INSPECTION READINESS
· PM responsible for the IR of the eTMF
· Coordinates all actions between the project team
· FUPs to ensure agreed TMF processes are followed
· Risk assessment, communication of issues & lessons learned, creation of CAPAs

STEP 5

READY FOR ARCHIVING
· TMF specialist performs a final quality review of the eTMF at the end of the study

BEYOND

ACTUAL ARCHIVING
· Archiving using Veeva software

METRICS

90%

TIMELINESS
From document issuance (vs. received) date: >= 90% passing documents submitted within 30 days
2020 results: 97.2%

98%

QUALITY AT POINT OF SUBMISSION
>= 98% of the documents submitted to be approved or approved with corrections
2020 results: 99.7%

90%

COMPLETENESS
>= 90% of TMF Milestones completed per expected planned finish date (+30 days)
2020 results: 98.7%

90%

REPLY TO QC ISSUES
90% of the QC issues closed within 30 days from the first time the QC issue was raised
2020 results: 91%

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THE POWER
OF VEEVA VAULT

Veeva Vault is **a cloud-based content management platform** and suite of applications that provides life sciences companies **a single source of truth to reduce complexity and increase business agility.**

VAULT eTMF

ENABLE REAL-TIME INSPECTION READINESS, VISIBILITY & CONTROL

- **REAL TIME INSPECTION READINESS**
- **INFORMED DECISIONS**
- **EFFICIENT OPERATIONS**
- **ALWAYS ACCESSIBLE**

HUB-BASED MODEL

eTMF REVIEWERS & SPECIALISTS

- **CRAS/CTAS IN COUNTRY**
- **REGULATORY AFFAIRS TEAM SUPPORT REGULATORY AND ETHICS**
- **PROJECT LEADERS**
- **VEEVA AS PREFERRED PARTNER**
- **ALL DATA HELD IN EUROPE**
- **STRUCTURED OVERSIGHT PLAN**

For further information, please contact xxx : **sromboli@excelya.com**