

## 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**

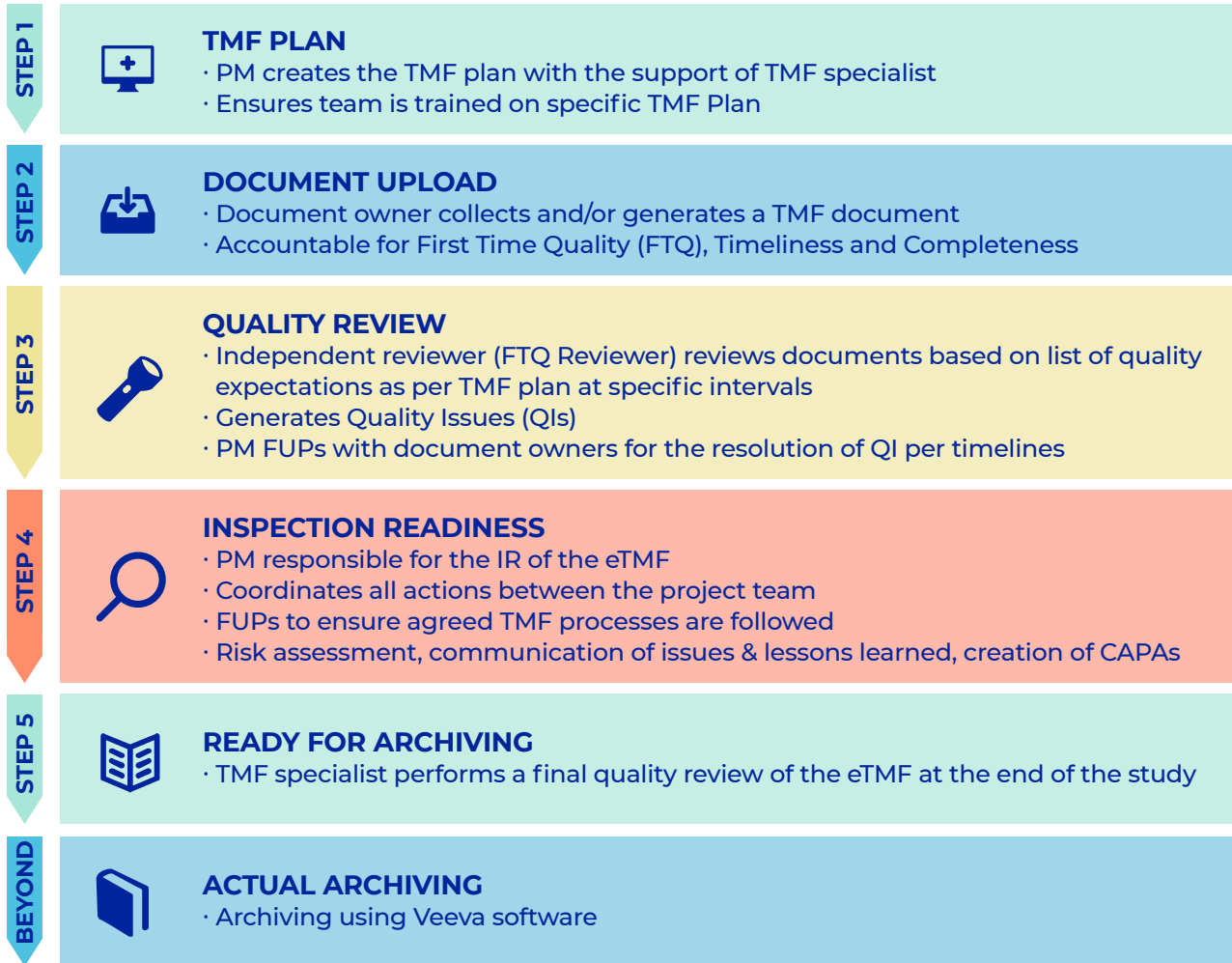
Metrics & markers to detect errors & gaps in eTMF on an ongoing basis

**#05**

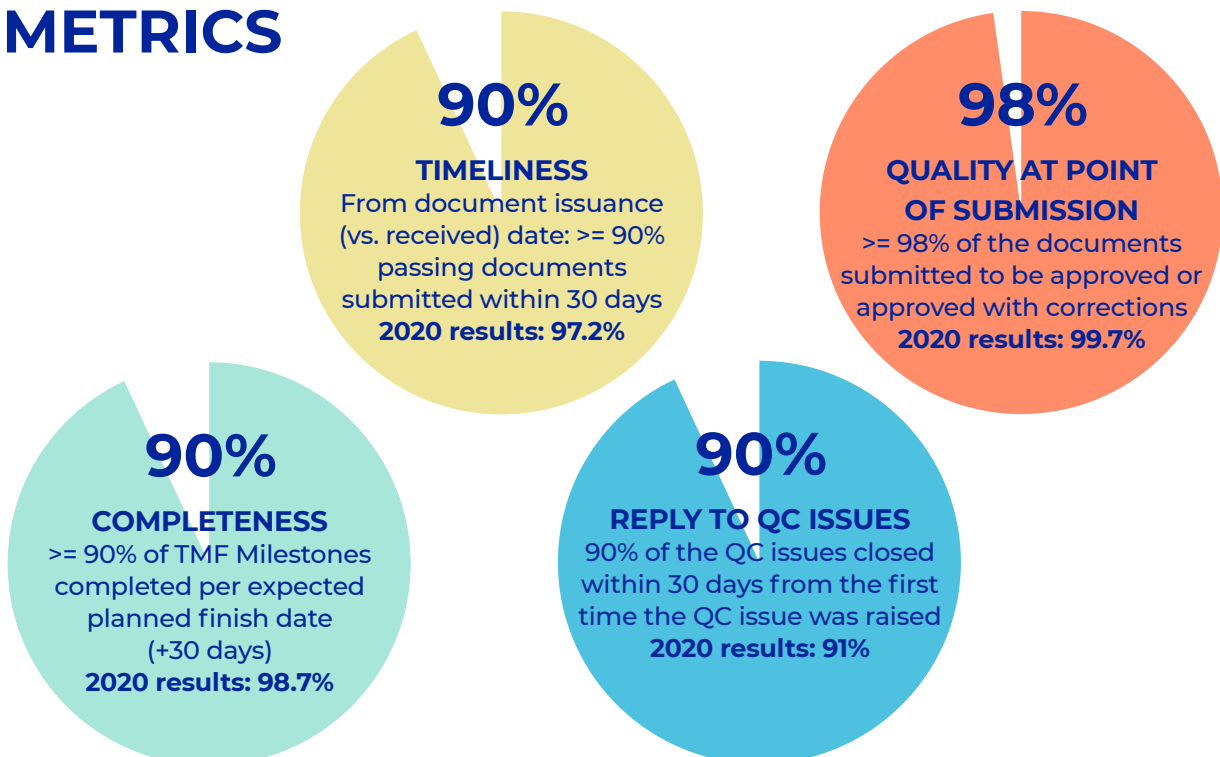
Final review with eTMF specialists to double check for quality

# eTMF WORKFLOW

## FULL-SERVICE SUITE INCLUDING eTMF



## METRICS





## 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



### HUB-BASED MODEL



**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 us at: [contact@excelya.com](mailto:contact@excelya.com)