

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

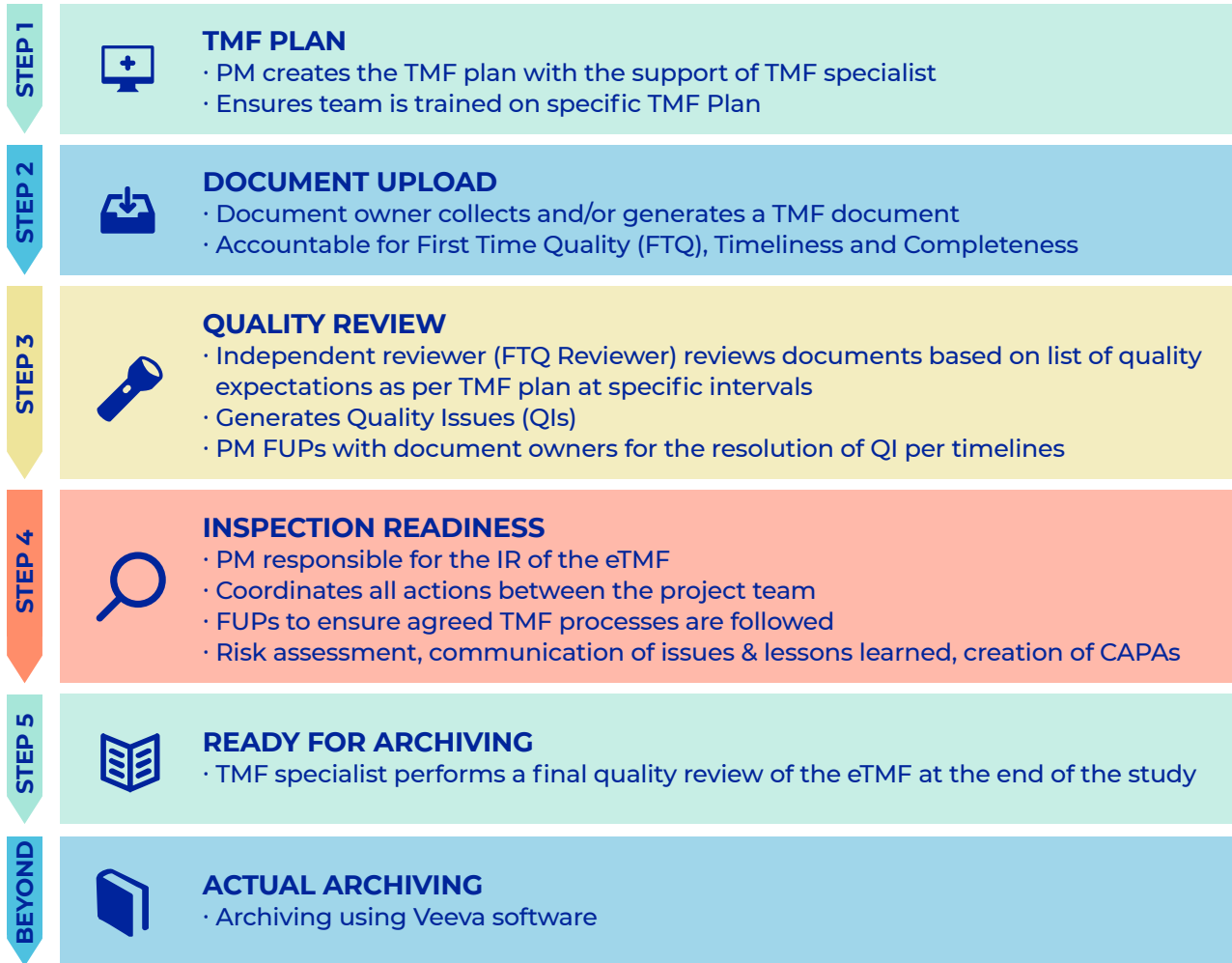
Metrics & markers to detect errors & gaps in eTMF on an ongoing basis

#05

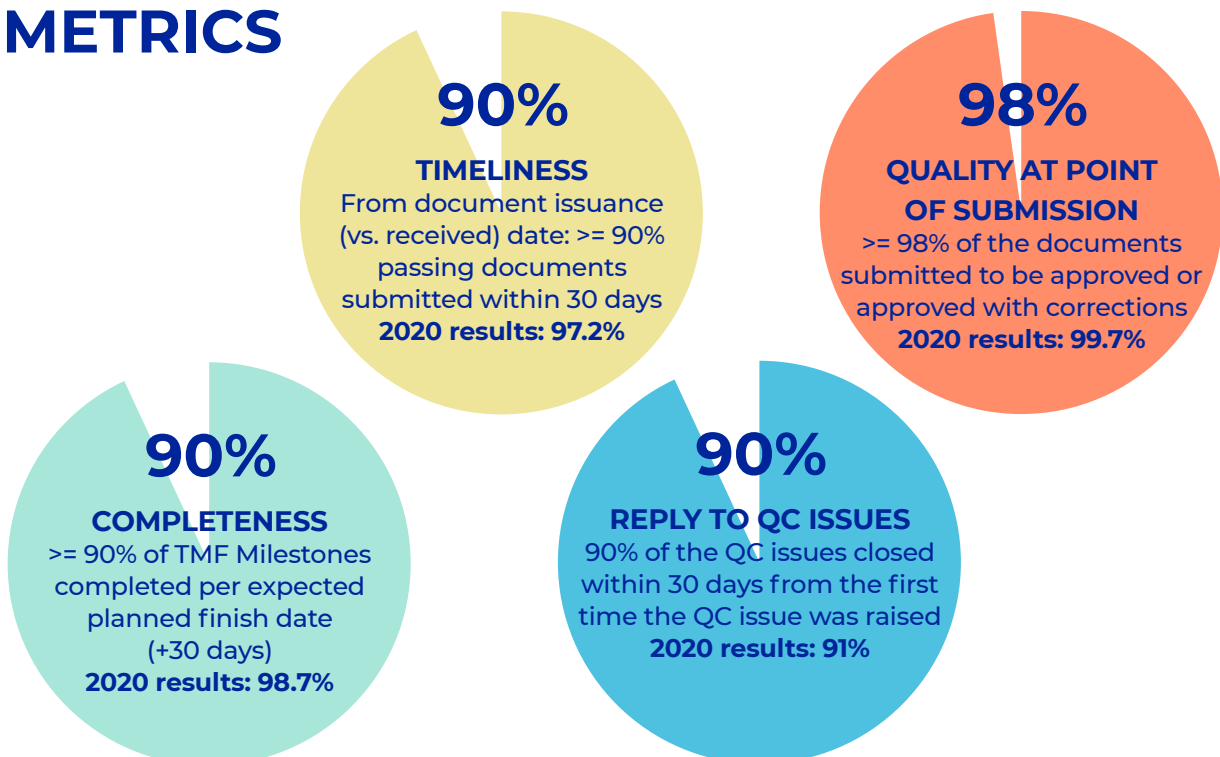
Final review with eTMF specialists to double check for quality

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 xxx : sromboli@excelya.com