

Incorporating Quality by Design into TMF Management

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**What Kind of Story
Do You Want To Tell?**



Fairytale



My Clinical Experience In Large and Small Biopharmas



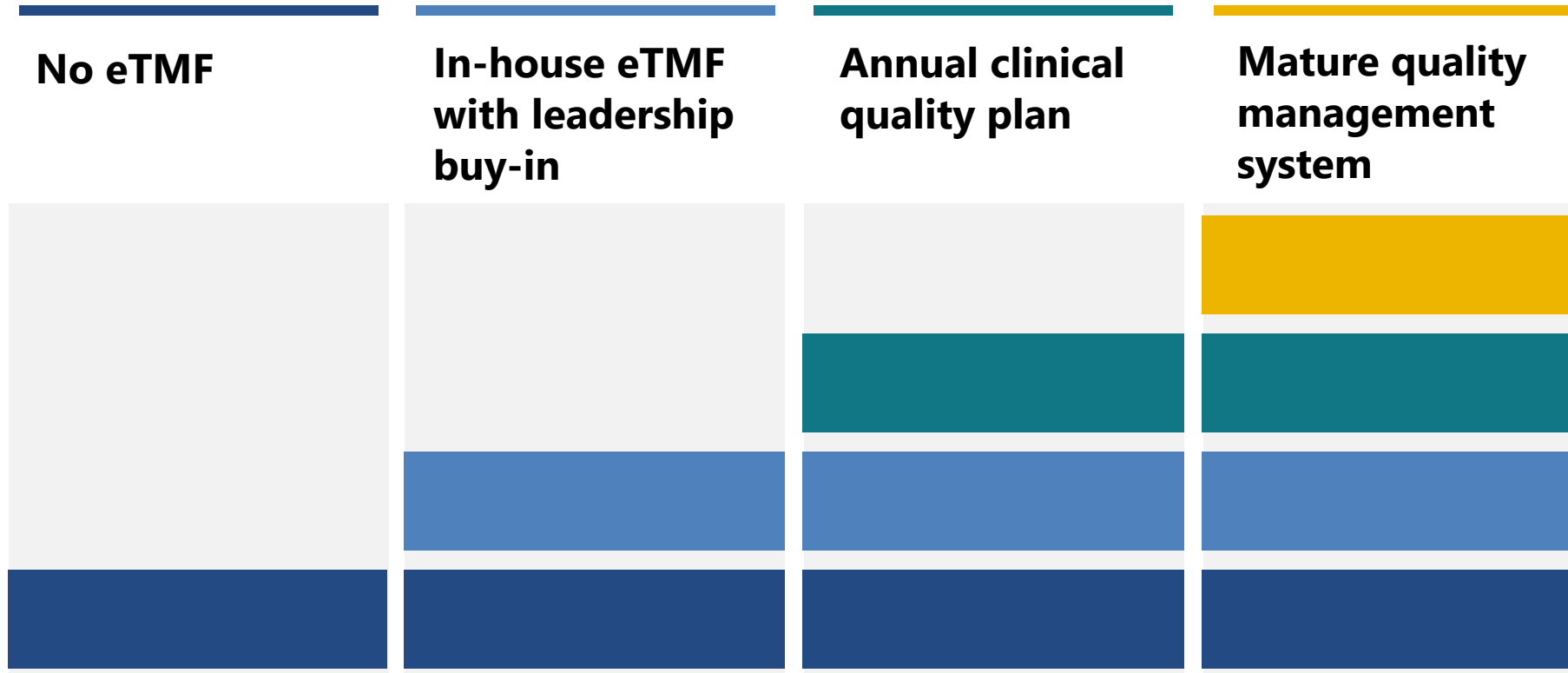
Large Biopharma Experience

TMF was drilled into everyone with fear

Small Biopharma Experience

Opportunity to take a strategic approach to TMF and quality from the beginning

Evolution: Starting With TMF Management



AffyImmune's TMF Operating Model

1

**CRO works in
AffyImmune eTMF**

4

**Clinical operations
team members**

1

Active study

Be Strategic

**Despite being
a 25-person
organization, we
prioritize owning
eTMF to improve
oversight.**

Quality by Design in TMF: Clinical Quality Plan

- ✓ **Identify new SOPs, policies, work instructions, forms/templates, and job aides needed**

- ✓ **Review and evaluate if existing controlled documents need changes**

- ✓ **Identify new training requirements**

- ✓ **Set completion targets at the quarter level**

Collaborate with Other Functions

Developed with the head of quality, the annual plan drives alignment across teams.

Criteria to Evaluate Clinical Quality Plan Annually

Headcount

**Outsourcing
strategy**

**Clinical
development
plans**

**New IND-enabling
programs**

Regulations

Efficiencies



Drama



Horror



TMF Insights for Larger Biopharmas

✓ **For CFOs and/or VCs:** help identify hidden costs and possible filing delays in an acquisition

✓ **For heads of clinical operations:** help identify needed resources for TMF cleanup

✓ **For IT leaders:** help rationalize the key data and documentation and migration strategy

Uplevel the TMF Conversation

Demonstrate to leadership that TMF due diligence is a critical piece of the M&A puzzle.

Benefits of QbD for Smaller Biopharmas

- ✓ **Improve TMF efficiency and scalability**

- ✓ **Fundraising/investor due diligence**

- ✓ **Demonstrate M&A readiness**

**Quality by
Design is for
All**

**It enables companies
to be strategic,
intentional, and
scalable.**

Clinical Quality Plan Evolves to Mature QMS

1

Quality by design
is for companies
of all sizes

2

Tailor your
messaging to the
specific goals of
other functions

3

Aim to tell a
consistent story
to regulators
and other
stakeholders