



Vendor Selection Blueprint: Getting the Right eTMF In-house

Bill, living with transthyretin amyloidosis, and his wife, Maura



TMF Week 2022

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Kate Santoro - Bio

- Director, Clinical Operations-TMF
 - Intellia Therapeutics
 - Cambridge, Massachusetts
 - Member of TMF Reference Model Change Control Board
- Previous Roles
 - Associate Director, TMF Operations – Deciphera Pharmaceuticals
 - Associate Director, eTMF – bluebird bio
 - Sr. Clinical Trial Manager – Alkermes
- eTMF Experience
 - Implemented 2 eTMFs
 - Currently implementing a 3rd
 - Completed vendor selection 3x
- Disclosure
 - The views expressed in this presentation are my own and may not represent views of Intellia



Today's Agenda

1 Bringing an eTMF in-house

2 Finding the Right Vendor

3 Assessing eTMF Vendors

4 Questions



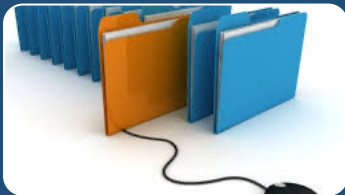
Are you ready to bring eTMF in-house?

What Does Your TMF Look Like?



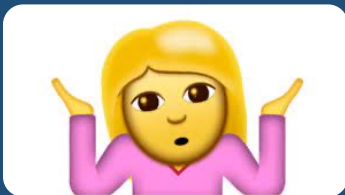
Chaos

- Hybrid: some paper/some electronic
- Random: held in several different places



Seemingly Controlled

- All electronic – different systems
- Managed by outsourced vendors/CROs



I Just Don't Know

- New to company
- New to TMF

Reasons to bring eTMF In-house

More Control

- Having better control of documents
- Oversight of CROs/vendors
- Negative experiences
- Inspection/audit response

Consistency

- Consistent processes across programs
- Same index/document map

Inspection Preparation

- Reinforce good documentation practices
- Eliminate gaps in documentation



Considerations

- When do you expect inspection?
 - Imminent
 - 1-2 years
 - >3 years
- What kind of document management process do you envision?
 - Centralized vs decentralized
 - TMF Team vs Content Owners
 - CROs and vendors vs internally managed



How do I find the right vendor?

Typical Vendor Selection Process



Identify Vendors



How Many Vendors Should I Look At?



How Many Vendors Should I Look At?

- Company Standard
- Previous Experience
- Preferred Providers





Vendor Search

- Google: 8-10 vendors
- Current Vendor
- What is the CRO using?
- TMF References
 - Industry Experts
 - Friends in the field
- What type of company do you want to work with?
 - Adopt new features?
 - Well established?
 - Ground-breaking?
- What are you looking for?
 - Vendors who provide exact features

Assess





Who Should Participate in the Demo(s)?

- Business Owner
 - TMF Team
- IT
- Potential System Users
 - Experienced
 - New to TMF
- Other Stakeholders
 - Quality
 - Validation
 - CROs



Vendor Assessment

Not All Vendors Are Created Equal

Company Size

- Large, mid-size, small

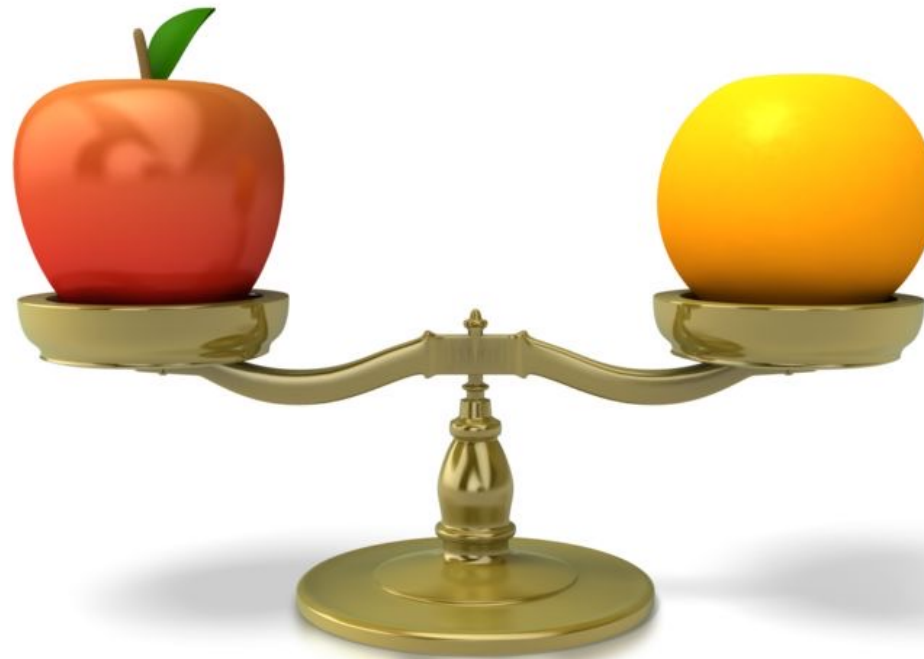
System Features

- User interface
- Migration and export

Reporting Capabilities

- Standard vs flexibility
- Dashboards vs reports

Compare





Vendor Scoring Tool

- List Important Features
 - Must-haves vs nice-to-haves
- Rate Each Vendor
 - Apple to apple comparison
 - Score scale (e.g., 1-5)
- Compare Vendor Scores
 - All participants complete
 - Compare scores and feedback

Example

| | Scoring (1-5 w/5=exceptional) | | | |
|------------------------|-------------------------------|-------------|-------------|----------|
| Criteria | Vendor #1 | Vendor #2 | Vendor #3 | Comments |
| User Interface | Score | Score | Score | |
| Document Management | Score | Score | Score | |
| Long-term Fit | Score | Score | Score | |
| IT Capabilities | Score | Score | Score | |
| Reporting | Score | Score | Score | |
| Managing System Access | Score | Score | Score | |
| Document Upload | Score | Score | Score | |
| | | | | |
| | Total Score | Total Score | Total Score | |



There Is No One Right Way

- Implementation #1 – no experience
 - Spoke frankly with CROs
 - Researched vendors (~5)
 - Conversations – asked questions
 - Demonstrations (~3)
 - Final Comparison
- Implementation #2 – some experience
 - Vendor already selected
- Implementation #3 – solid experience
 - Researched 3 vendors – demonstration
 - Narrowed to 2 selections
 - Head-to-head comparison
- Implementation #4 – solid experience
 - Preferred provider + comparator
 - Demonstrations
 - Head-to-head comparison



Q + A

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