



Presented by

Paul Fenton  
Steph Viscomi

Date

May 25<sup>th</sup>, 2021

# How to Manage a Multi-Vendor eTMF Ecosystem Effectively

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# Housekeeping

- This session will be recorded and made available to all registrants
- All recordings will be available on demand via a link sent following each event
- The Certificate of Attendance will be provided at the conclusion of the eTMF Bootcamp series
- Registrants must attend at least 1 eTMF Bootcamp session to receive the certificate



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DAY 1

## TMF Health & Metrics

DAY 2

## Site TMF & Investigator Site Files

DAY 3

## The Sponsor & CRO Environment

DAY 4

## Inspections, Standards & Regulations

DAY 5

## eClinical Technology & The Future

# Your speakers today



**Paul Fenton**

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# Paul Fenton

President & CEO



Paul Fenton holds a degree in management from London Metropolitan University as well as an MBA in Technology Management from the Université du Québec à Montréal.

Paul has significant industry experience at a senior management level in the development, deployment and management of computerized systems for use in regulated clinical trials. He co-founded Montrium in 2005. He has worked on major clinical technology projects both in Europe and North America and has a strong background in CDISC and ICH standards as well as in the integration of systems and processes for clinical trials. He is a regular speaker at industry events and is actively involved in several projects for the development of clinical research standards and platforms.

- Started career at major EU CRO
- Over 20 years of experience in Pharmaceutical industry
- 15+ years directly in Trial Master Files
- Speaker, Instructor, Co-Chair, Advisory Board Member for multiple TMF industry conferences



# Stephanie Viscomi

AD TMF Operations, Alexion



## Industry Experience

- 13 years Pharmaceutical / Biotech
- CRO & Sponsor
- 7+ years Direct TMF
- Managed Global TMF Teams / Vendors
- Speaker, Instructor, Co-Chair, Advisory Board Member for multiple TMF industry conferences

## OFFICIAL DISCLAIMER

THE VIEWS AND OPINIONS EXPRESSED IN THIS PRESENTATION ARE STRICTLY THOSE OF THE AUTHORS.

THESE DO NOT REPRESENT OFFICIAL POLICY OR POSITION OF ALEXION.

Currently manage a multi-level TMF Operations team of 12 people with a centralized operating model.

Our remit includes five (5) CRO Partners, three (3) different study models, eight (8) eTMF systems across 70 studies.



# POLL

Is your Organization a ....

- a) CRO
- b) Sponsor
- c) Something else



# POLL

**What is your current TMF Strategy?**

- a) Outsourced
- b) Insourced
- c) A mix of A & B



# Managing Multiple Vendors (MVM)



## Process

Consistent and effective end-to-end processes

Different vendors/systems may require minor process adaptations. Ensure the SOP is open enough for required process modifications as needed.

Implement Effectiveness Checks to verify the process is still working even as people and technology change.



## Technology

Can consistent processes align with all systems? If no, what changes need to be made?

How can technology modify my process (i.e. placeholders and oversight)?



## People

Communication from Leadership to Contributor level

Regular communication touchpoints

# Get Back to Basics!

Whether you have been managing multiple vendors or just stepping into a role to get it all organized, remember the basics and build from there...

## Current TMF Operating Model?

- Outsourced? Insourced? Combo?
- Internally Centralized? Decentralized?

## Current Operating Logistics?

- Systems?
- Processes?
- Templates? TMF Plan, TMF Template

## TMF Cheerleaders

People within your organization who will either help and/or support the TMF goals?

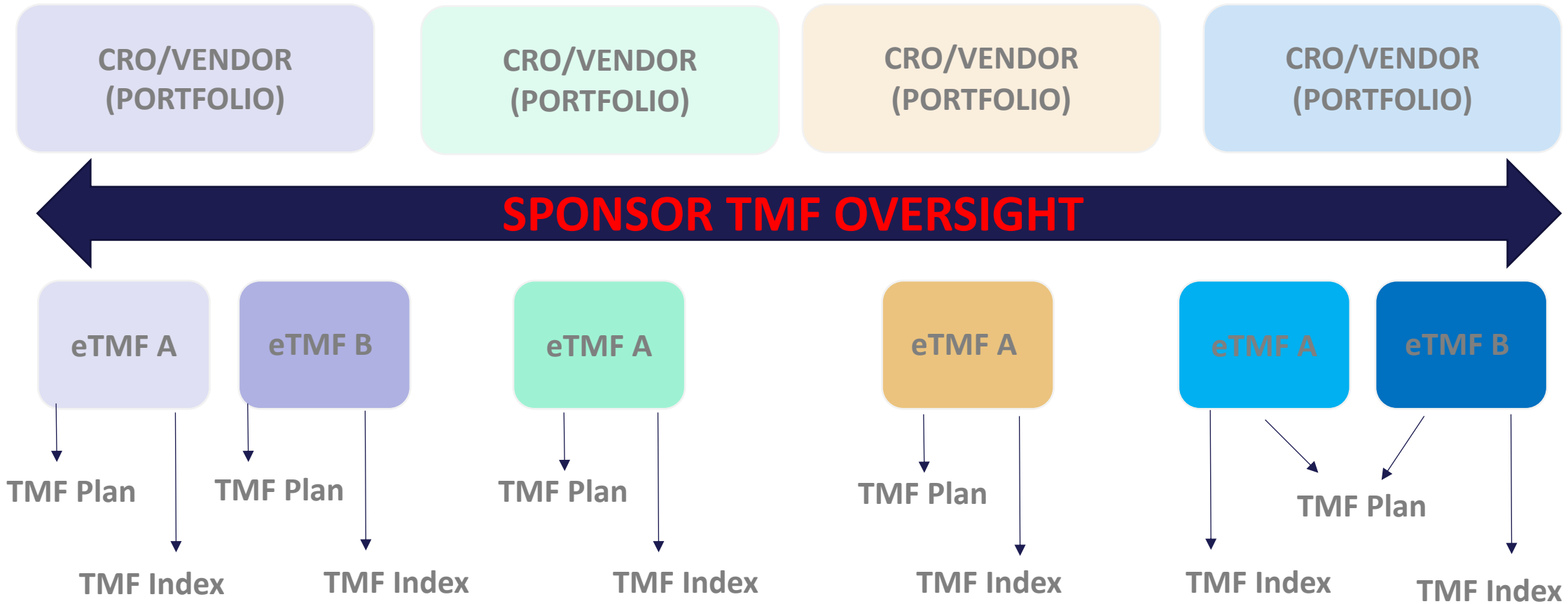
## SOP's

- Know and Understand the TMF requirements
  - Requirements for QC
  - Document upload requirements
  - TMF Plan/Index requirements

## Vendors

- CRO(s)/Sponsor(s)
- Document Processing Vendor

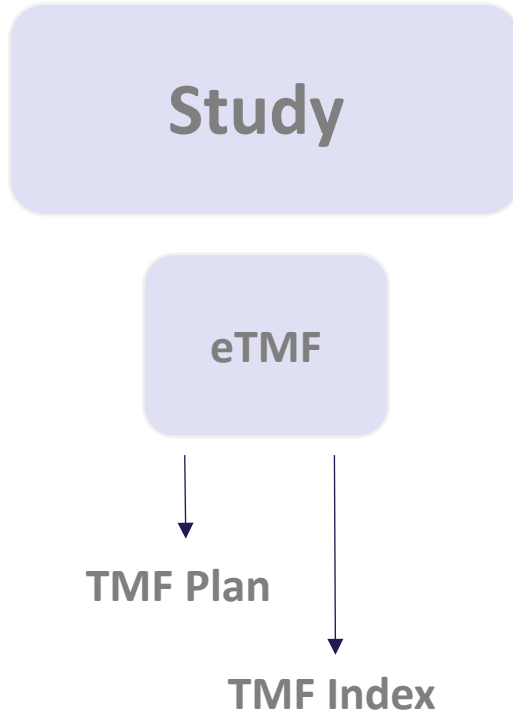
# Outsourced TMF Strategy Approach



# Start from the Bottom Up

## Study Level

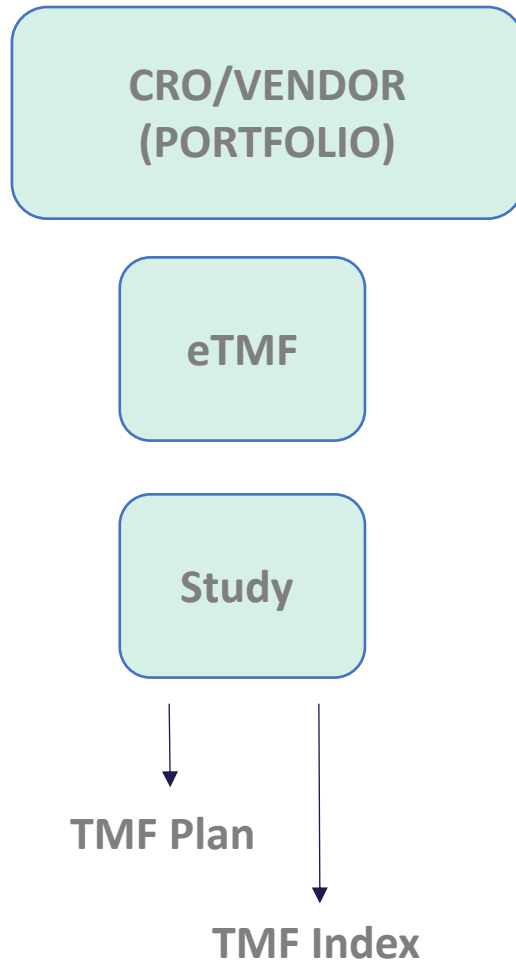
14



- **What are the study specifics?**
  - Phase?
  - Countries? Sites?
  - Key Milestone Dates: Protocol Approval? Database Lock? CSR?
- **Who is the CRO or Sponsor partner?**
  - Who are the TMF/Study team counterparts?
- **eTMF System**
  - Who owns it? Sponsor? CRO?
  - What does access look like? Do all team members have uploading capabilities? Or only system owner?
- **What are the requirements for each study?**
  - Is the correct study specifics/processes identified in the TMF Plan/Index?
- **Is the study team educated with the current TMF processes and eTMF system (i.e. document upload process? QC requirements?)**

# Start from the Bottom Up

## Portfolio Level

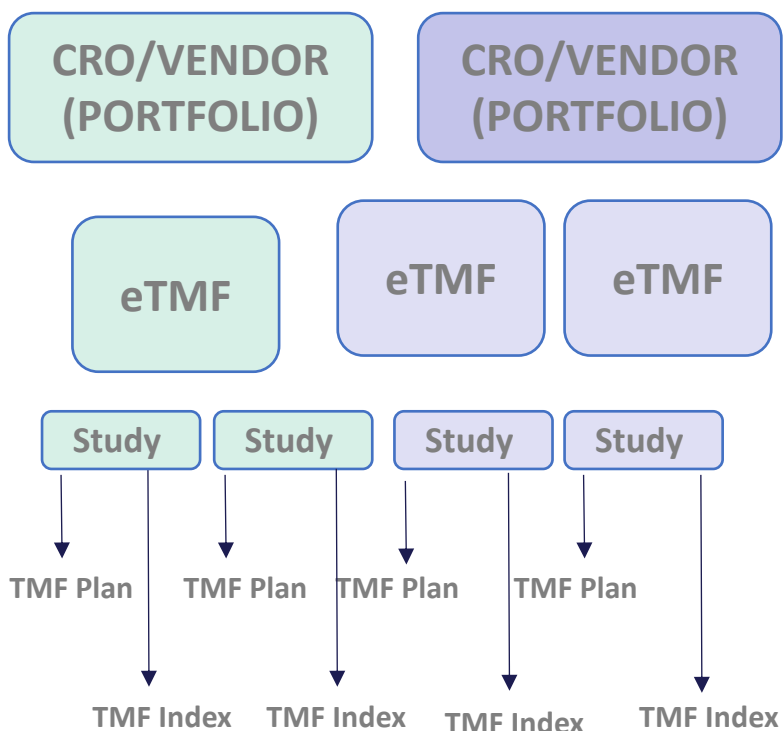


- **Who is the CRO or Sponsor partner?**
  - Who are the TMF/Study team counterparts?
- **eTMF System**
  - Who owns it? Sponsor? CRO?
  - What does access look like? Do all team members have uploading capabilities? Or only system owner?
  - Access Request / Deactivation Process?
- **Portfolio Level Processes / Templates**
- **Portfolio Key Performance Indicators**
  - Metrics Delivery
- **Communication / Relationships**

- **Portfolio Level TMF Program Plan**
  - Portfolio Logistics – systems
  - Processes for each party
  - Roles & Responsibilities

# Start from the Bottom Up

## Cross Portfolio Level



### Who is the CRO or Sponsor partner?

- Who are the TMF/Study team counterparts?

### eTMF System

- Who owns it? Sponsor? CRO?
- What does access look like? Do all team members have uploading capabilities? Or only system owner?
- Access Request / Deactivation Process?

### Portfolio Level Processes / Templates

- Are processes consistent across all portfolios?

### Portfolio Key Performance Indicators

- Metrics Delivery
  - By Leadership
  - By TMF Contributors

### Education

- Is your organization receiving the right and consistent TMF education and information?

### Communication

- Ongoing Touchpoint meetings w/stakeholder

### TMF Operations Program Plan

### TMF Operations Compliance Plan

- High priority study effectiveness checks

### Internal/External Partnerships

- TMF Cheerleaders?
- Leadership?
- TMF Governance Team?
- TMF Core Team?
- Quality Partners?



# Multiple Vendor Management Challenges

## Too Many eTMF Systems (8 Total)

- ❖ Frustrating to deal with multiple systems
- ❖ Obtaining access and system training is not easy

## Lack of TMF Understanding / Process Knowledge

- ❖ Does not understand what a TMF is or why we need it
- ❖ Lack of understanding on how to complete QC or what to QC

## TMF Content Owner

- ❖ “Function documents in different system, therefore not TMF applicable”
- ❖ “Documents do not belong to my function”

## Time/Resources

- ❖ I don't have time

## Process Consistency

- ❖ Process modifications

## Leadership Support

- ❖ May have it in one place, not others

## Not all systems are created equal

- ❖ Upload processes
- ❖ Reporting / Metrics Capabilities
- ❖ Overall Sponsor level access

## Communication

- ❖ Internally & Externally
- ❖ Leadership
  - ❖ TMF Counterparts
  - ❖ Study Teams

## Change Management

## Stakeholder involvement

- ❖ i.e. TMF Content Ownership

Simple  
Keys to  
Success





Each individual piece ***People, Process and Technology*** plays a unique role on its own. Having them work in unison can build a baseline a of **success** for a powerful and operational multi-CRO/vendor TMF team.

# #1 Communication is Everything



When managing multiple vendors, systems, studies, etc., it is key to build foundational relationships with your internal and external counterparts.

Building relationships will allow open dialog on building unified processes, providing praise, discuss difficult issues, etc.

Good to have a point of contact at each vendor/CRO as direct individual to continuously connect with on daily activities and ad-hoc issues

# #2 Consistency is Key



## Process

Ensure processes are consistent across all portfolio and studies – to the extent possible

Don't allow for process deviation unless absolutely required



## Templates

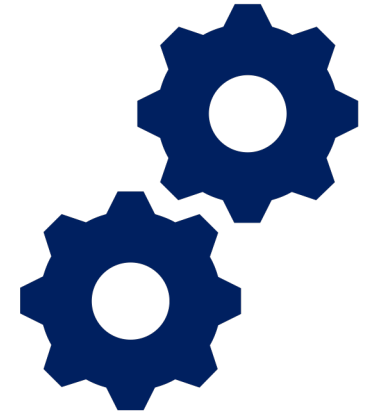
Creating consistent templates (i.e. TMF Plan, TMF Index, TMF QC Reports, etc.) to be used across portfolios will prove as beneficial to ensure efficiency.



## Communication

Set consistent expectation across teams, vendors, etc on how communication is handled.

Set expectation how TMF information and metrics delivery will be shared with teams.



# #3 eTMF System(s) are our Baseline

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## Know your eTMF Capabilities and Features

- How is it configured?
- Does it have placeholders?
- How can documents be uploaded? (Drag and drop? Batch? Native Format?)
- Can QC's be completed in system?
- What does the EDL (expected document list) process and oversight look like?
- What are the reporting capabilities? Do you have access to use the reports?

## If multiple systems...

- How do the processes differ? (i.e. document upload, QC?, understanding completeness?)
- How is access set-up for each eTMF
  - Who owns/drives the process





# #4 Plan, Engage and Attack



## Attack Today!

How will you stay organized? OneNote? Outlook? Paper/Pen?

What is TODAY'S priority

## Engage Stakeholders

Encourage feedback, Suggestions, Ideas!

## EDUCATE

Build knowledge of TMF stakeholders, both contributors and leaders

## ENHANCE

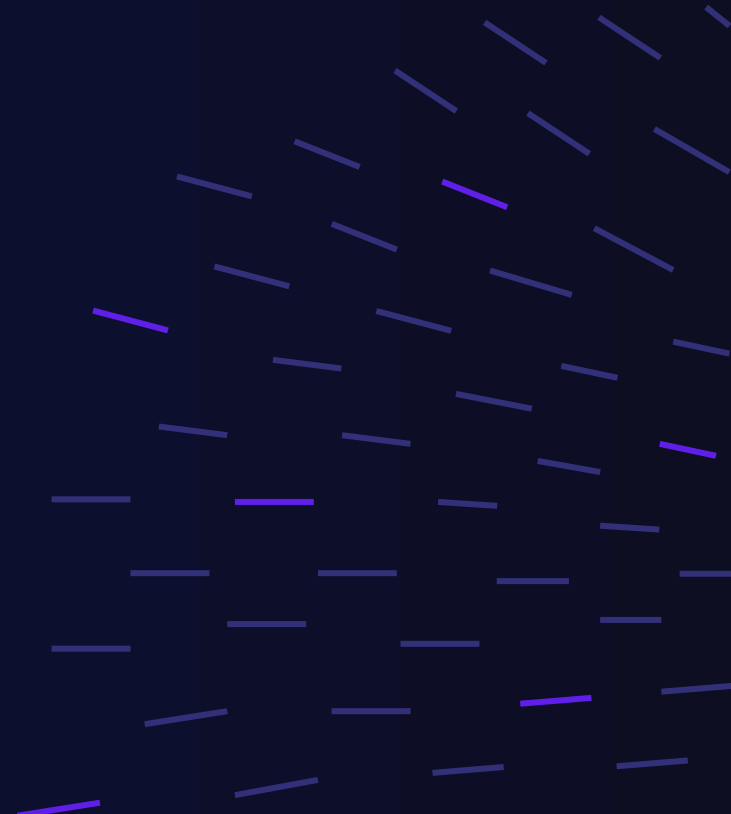
Improve processes and overall TMF health from feedback and suggestions from TMF stakeholders



Section 2

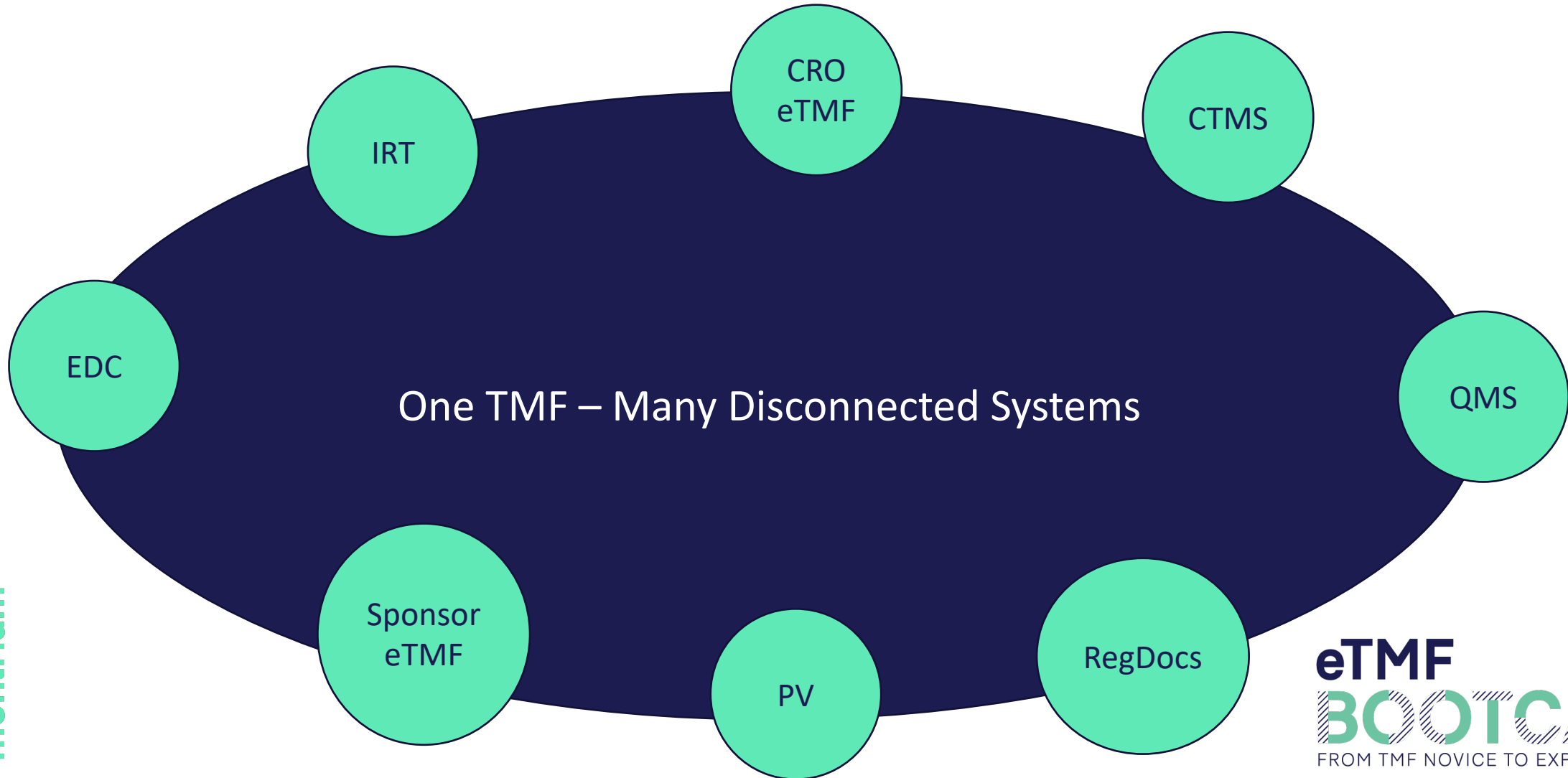
# Technological Considerations

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# Technology Landscape in 2021



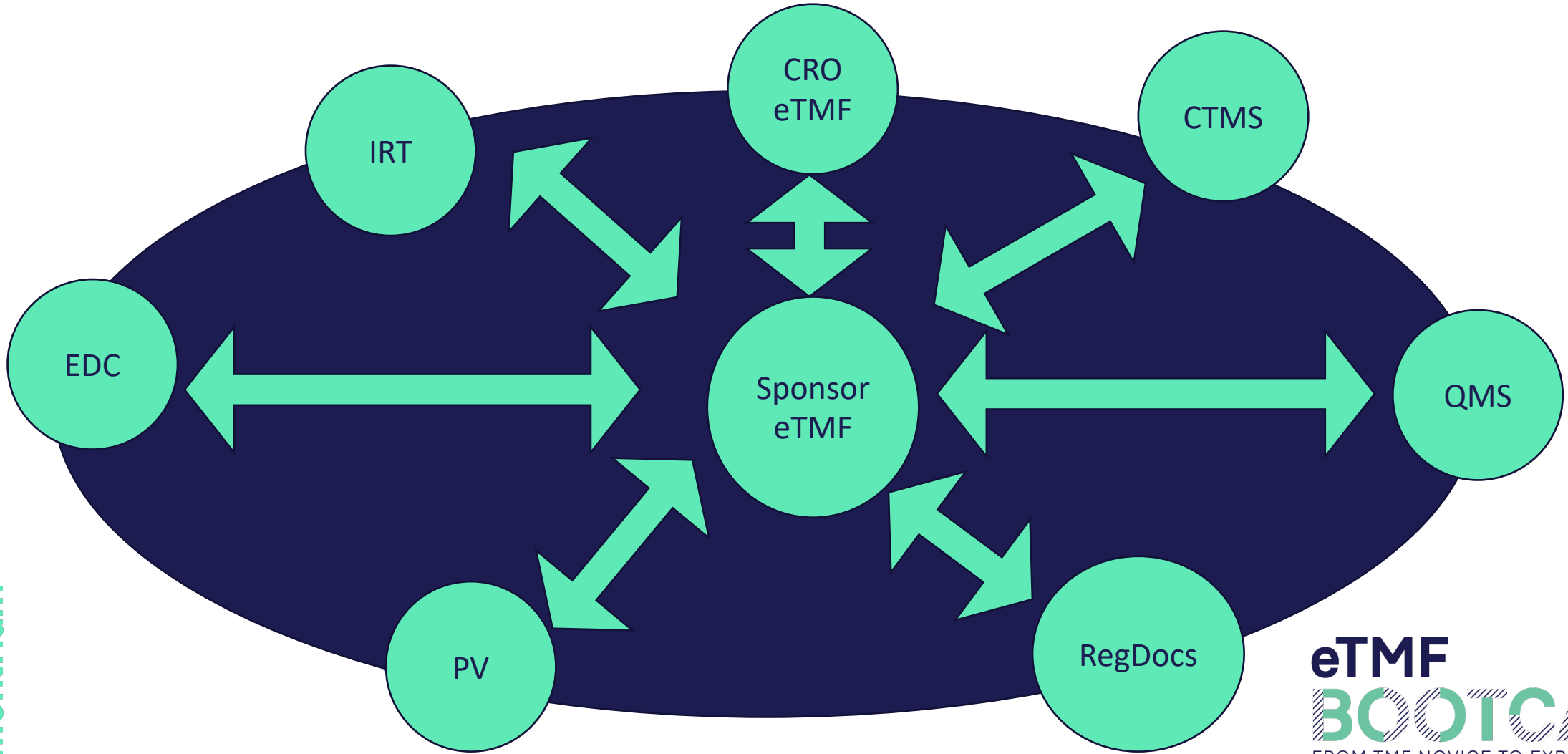
# We need a new model

- **Completeness**
  - It is impossible to be able to accurately calculate completeness if artifacts are stored in different systems
  - Definition and management of completeness is often in the eyes of the beholder
- **Oversight**
  - Sponsors need to be able to see all content in one place
  - Sponsors need to be able to collaborate with CROs electronically

# We need a new model

- Remote Inspections
  - Many systems and organizations can make remote inspections challenging on many fronts
  - Records have to be readily available for inspection
- Clustering and Process View
  - The TMF must tell a story and often artifacts need to be clustered around specific processes to help clinical teams and inspectors understand what happened
  - In a process-based approach, the need for artifacts can often be triggered by events that occur in the study

# We need better interchange...



# Standardization is key

- We need to be able to interchange data, artifacts and event information between systems and organizations
- To do this we need to be able to standardize on the format and nomenclature of this information
- The Exchange Mechanism and TMF RM are focused on this
- Without industry standards interchange is challenging and expensive

# Future directions

- Automated interchange or linking
  - Implementation and expansion of the EMS will help with integration of systems
  - Other standards for clinical data i.e. CDISC could also be leveraged to access relevant clinical data directly in the TMF
  - Content could be transferred or linked to to allow for easy access and comprehensive completeness calculations
- Event based messaging
  - TMF content is dictated by activities and events in the study
  - We could leverage the EMS as a means to send messages indicating that specific events or milestones have occurred
  - This would allow for better oversight and better TMF metrics

# Future directions

- Clustering around processes
  - We need to stop thinking of the TMF as just a repository and think of it as a process management and reporting tool
  - We need a way to cluster artifacts across system and organizational boundaries
- TMF Health tools
  - We will start to see intelligent tools and system features which will allow us to get a better handle on overall TMF health
  - These tools will include things like anomaly detection and risk calculation



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**Thank You!**



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