

# From Insight to Impact: Driving Resilient and Compliant TMFs through Smarter Decision Making

Janice Cassamajor and Angie Gill

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**From Insight to Impact: Driving Resilient and Compliant TMFs  
Through Smarter Decision Making**

Janice Cassamajor, Director Global Program Management, Cencora  
Angie Gill, Lead Customer Success Manager, Cencora

# Meet the Speakers

## Janice Cassamajor

**Title:** Director Global Program Management

**Organization:** Cencora



Janice Cassamajor is a customer-focused leader with over 15 years of experience in the life sciences industry. Her career spans clinical operations, regulatory affairs, and Trial Master File (TMF) management. For the past six years, Janice has brought her deep industry expertise to the vendor side, cultivating strategic partnerships and driving innovation in TMF and regulatory solutions. As a dedicated mentor and coach, she is passionate about empowering others to reach their full potential.

## Angie Gill

**Title:** Lead Customer Success Manager

**Organization:** Cencora



Angie Gill is a dynamic Lead Customer Success Manager based in Pennsylvania, with a strong track record of driving client success across diverse industries. Angie blends her expertise in life sciences, data analysis, and sales to deliver strategic insights and build lasting partnerships. Her analytical mindset and customer-first approach enable her to align business goals with impactful solutions, ensuring high levels of satisfaction and retention. Angie is known for her collaborative spirit, attention to detail, and commitment to continuous improvement.

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# Agenda

1. The Evolution of Data in TMF Management
2. Leveraging TMF Metrics and Industry Benchmarks for Smarter Decisions
3. Turning Data into Trust: Storytelling That Drives Strategic Decisions





# The Evolution of Data in TMF Management

# Nashville, TN: Country Music Hall of Fame (CMHF)

Honors singers,  
songwriters, and  
other figures who  
have made  
significant  
contributions to  
country music



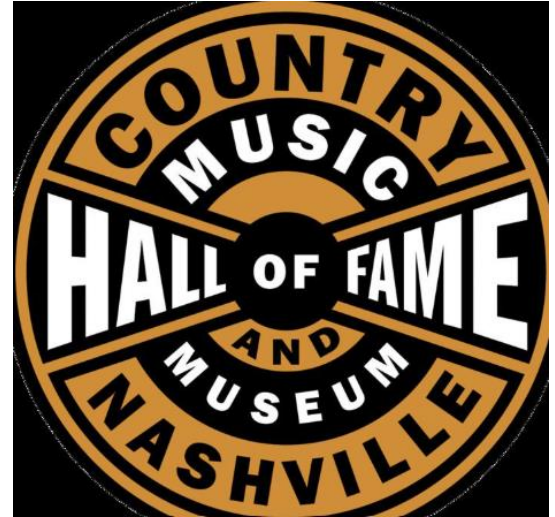
Changes since its  
inception in the  
1960s continue to  
redefine successes  
of the country music  
landscape



# Audience Insight Brain Teaser CMHF



What factors would you determine on assessing who would be inducted in the Country Music Hall of Fame?





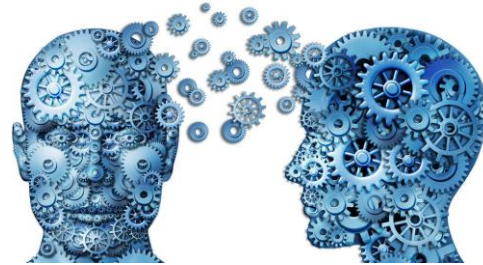
# Evolution of CMHF Induction Criteria

Criteria	1960s-1980s	1990s-2000s	2010s-2020s
Focus on Traditional Artists	✓	✓	—
Posthumous Recognition	✓	✓	—
Industry Insider Influence	✓	✓	—
Inclusion of Subgenres	✗	✓	✓
Recognition of Non-Performers	✗	✓	✓
Gender Diversity	✗	—	✓
Genre-Blending Acceptance	✗	—	✓
Timely Inductions	✗	✗	✓



# Audience Insight on TMF Management

How can you positively impact your TMF Health by utilizing data and industry expertise to assess areas of opportunity of focus?



# Evolution of TMF Management

1. Paper-Based TMFs (Pre-2000s to Early 2000s)

2. Early Electronic TMFs (eTMFs) (Mid-2000s)

3. Advanced eTMFs (2010s)

4. Intelligent eTMFs (2020s–Present)

5. The Future of TMF Management



# Differences to Consider Between Sponsors/CROs

 1. Sponsor-Specific TMF Structures

 2. Reporting Frequency and Depth

 3. Compliance and Audit Readiness

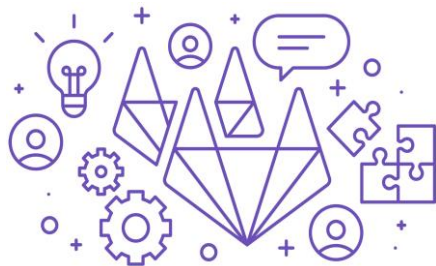
 4. CRO vs Sponsor Reporting

☐ 5. Use of TMF Reference Model

 6. Strategic vs Operational Reporting




# Effective Collaboration



***TMF Reference Model v4 anticipated in early 2027!***



# Proactive versus Reactive TMF Management

Feature	 Proactive TMF Management		Reactive TMF Management
Timing	Ongoing		End-of-trial
TMF Health Monitoring	Regular		Sporadic or last-minute
Audit Readiness	Continuous		Just before inspection
Risk Level	Low		High
Collaboration & Oversight	Strong		Limited
Cost & Efficiency	Optimized		Potentially high

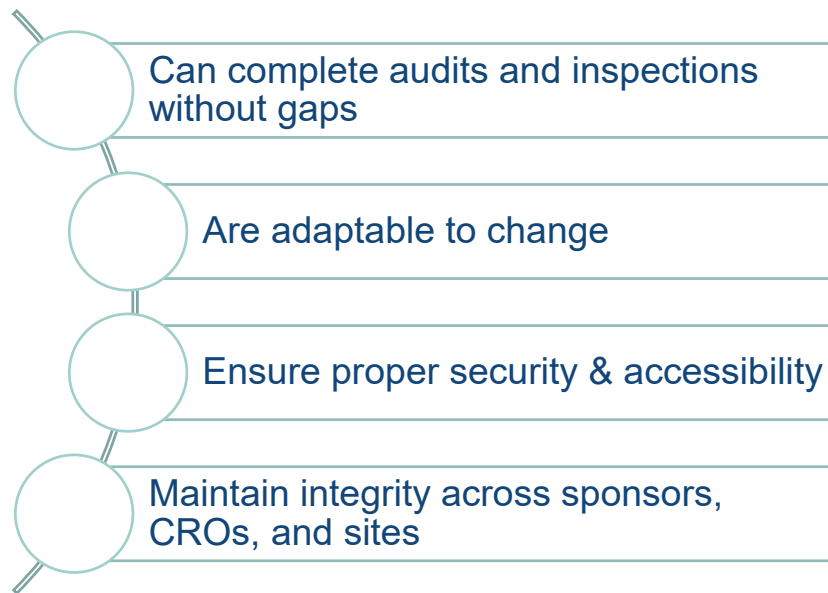
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## Leveraging TMF Metrics and Industry Benchmarks for Smarter Decisions

# Where Insight Begins

## Resilient TMFs



## Internal Metrics tell you:

- How you are doing
- The general health of your TMF and if you are “inspection ready”



## Industry Benchmarks tell you:

- What “good” looks like
- Where to focus improvement efforts

# Internal TMF Metrics >>>

## Timeliness

- The time taken from the record ready to file to available in the TMF.

>90%  
80-90%  
<80%

## Quality

- The pass rate of each record entering the TMF.

>95%  
85-95%  
<85%

## Completeness

- A measurement of what is expected to date vs what is present in the TMF.

>90%  
80-90%  
<80%

# Industry Benchmarks

## >95% COMPLETENESS

Measures the ratio of expected vs. filed documents

## <5% QUALITY

Percentage of documents flagged during QC due to errors

## 80-90% TIMELINESS

Business days from the date a document is created to when it is filed in the eTMF

## Bi-Annual

### RECONCILIATION

Regular matching of site documents with TMF records to ensure consistency

## Bi-Annual

### QR REVIEW FREQUENCY

Bi-annual QR reviews across all TMF zones

## Rejection Rate

### DOCUMENT LIFECYCLE

Time from draft to final filing/ longer durations may indicate workflow inefficiencies

## Red/Yellow/Green

### RISK INDICATORS

Red/yellow/green flags in TMF dashboards indicate risk status

# Global Trial Perspective

## Top 5 Countries Submitted to:



- United States
- Australia
- United Kingdom
- Canada
- Germany

## Top 5 Query Types

**36%** Metadata Issues

**21%** Misfiles

**16%** Document Quality

**10%** Deletion Request

**7%** Duplicate Documents

## Top 5 Documents Submitted



**= 68%**  
of Total Documents

### Fun Fact: Misfiles

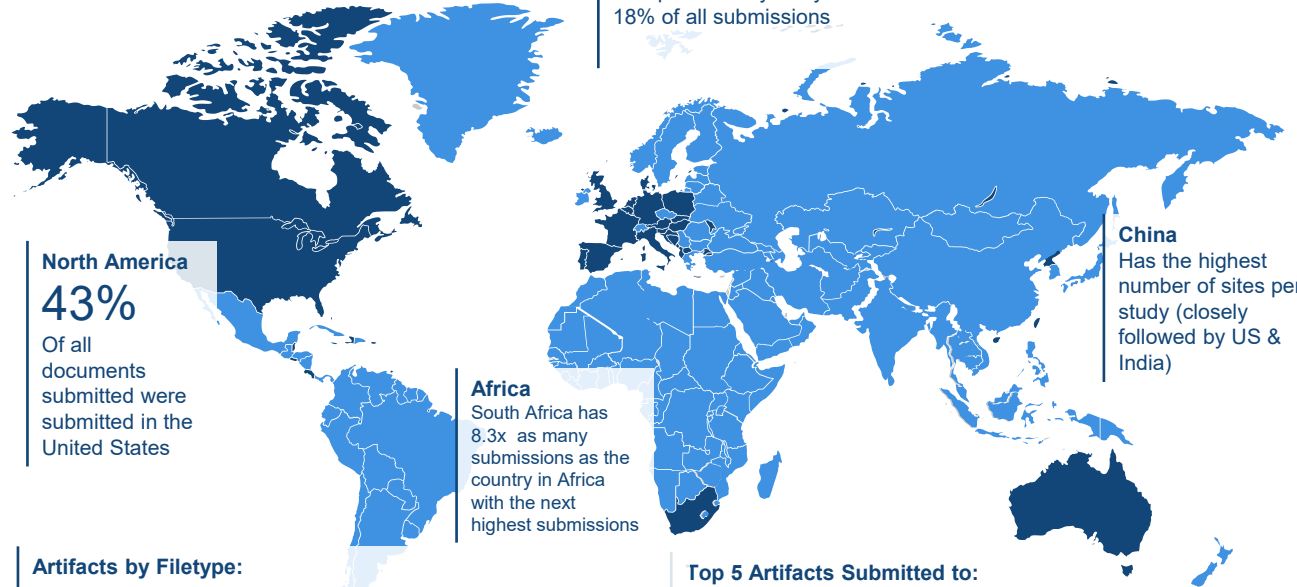
1/4 of misfiles are at Sub-Artifact level

### Europe

6 of the top 10 countries are in Europe and they carry about 18% of all submissions

■ Top 20 countries

■ Remaining Countries



### Artifacts by Filetype:

**Site**  
**74%**

**Trial**  
**19%**

**Country**  
**7%**

### Top 5 Artifacts Submitted to:

- 05.04.03 Monitoring Visit Report
- 05.02.07 Site Staff Qualification Supporting Information
- 05.05.01 Relevant Communications
- 05.03.03 Site Staff Evidence of Training
- 02.02.03 Informed Consent Form

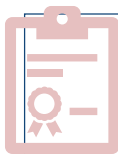


# Sample Metrics Categories



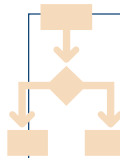
## TMF Health & Completeness

- % of artifacts filed vs. expected
- Missing documents by section or country
- Timeliness of document filing



## Quality & Compliance Metrics

- Audit/inspection
- QC error rates
- Deviation trends



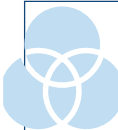
## Process Efficiency

- Cycle times for document review/approval
- Bottlenecks in document flow
- Processing guidance effectiveness



## System Usage & Behavior

- User activity by role or location
- Document upload patterns
- Training completion rates



## Study & Site Level Comparisons

- TMF performance by study phase or therapeutic area
- Site-level document compliance
- Country-level trends



## Vendor Oversight

- CRO performance on TMF deliverables
- Third-party document quality
- SLA adherence



## Historical Trends & Forecasting

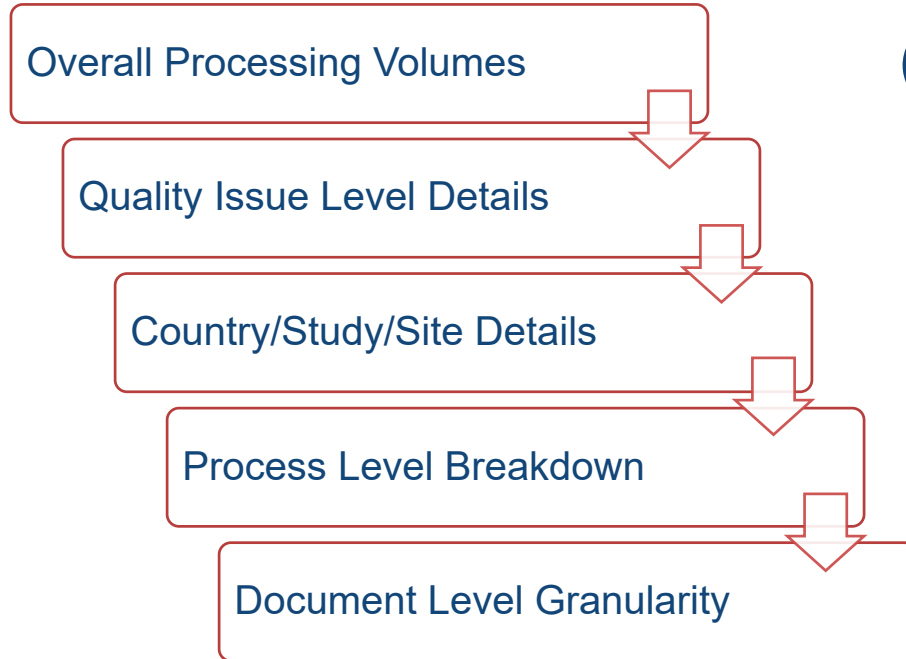
- Volume trends
- Year-over-year TMF health improvements
- Predictive insights (e.g., risk of inspection findings)



## Innovation & Automation Impact

- AI/ML usage in TMF (if applicable)
- Automation of QC or filing
- ROI from digital tools

# Drilling Down to Meaningful Quality Metrics (Processing)





b.

Month	Docs	Queries	Query Rate
January	82,216	15,226	19%
February	88,123	16,070	18%
March	105,848	17,626	17%
April	82,499	14,460	18%
May	82,020	13,904	17%
June	75,041	16,495	22%

3. Transmitter Company:

a.

TRANSMITTERCOMPANY	Up to 7 Days	Up to 14 Days	Up to 30 Days	Over 30 Days
	14		3	14
	65	8	2	10
	215	10	1	49
	153	4	4	1
	308	55	114	45
	48	23	4	7
	71	12	9	

2. a. Month:

QueryCategory	Open	Closed
Default	5	679
Duplicate	6	252
Expired Document	1	73
Incorrect Information	44	1,008
Metadata error	95	7,921
Misfile (reallocate)	39	2,843
Missing Translation Documents	15	114
Visual quality error	122	3,278
<b>Total</b>	<b>327</b>	<b>16,168</b>

b. Protocol:

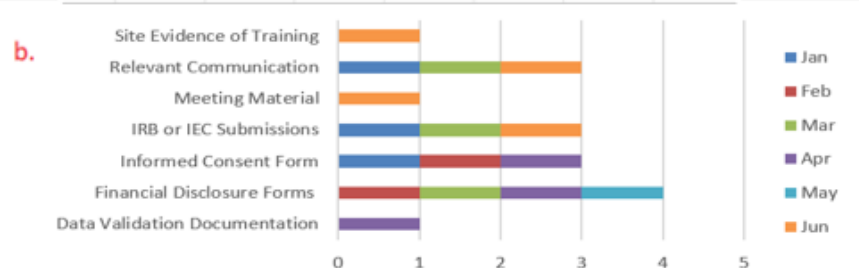
PROTOCOL	Approved	Rejected	Query Rate	Open	Closed
	41	111	73.03%	41	93
	442	231	34.32%	36	202
	752	345	31.45%	32	368
	21	15	41.67%	21	
	766	334	30.36%	18	357
	162	114	41.30%	17	124
	451	111	19.75%	13	122
<b>Total</b>	<b>60,799</b>	<b>14,242</b>	<b>18.98%</b>	<b>327</b>	<b>16,168</b>

b.

TRANSMITTERCOMPANY	January	February	March	April	May	June
	4%	2%	4%	5%	1%	2%
	14%	20%	13%	10%	19%	6%
	12%	8%	18%	7%	13%	18%
	10%	4%	4%	10%	4%	10%
	19%	20%	19%	26%	27%	34%
	15%	8%	10%	11%	6%	5%
	8%	14%	15%	12%	7%	6%
	11%	10%	7%	9%	9%	6%

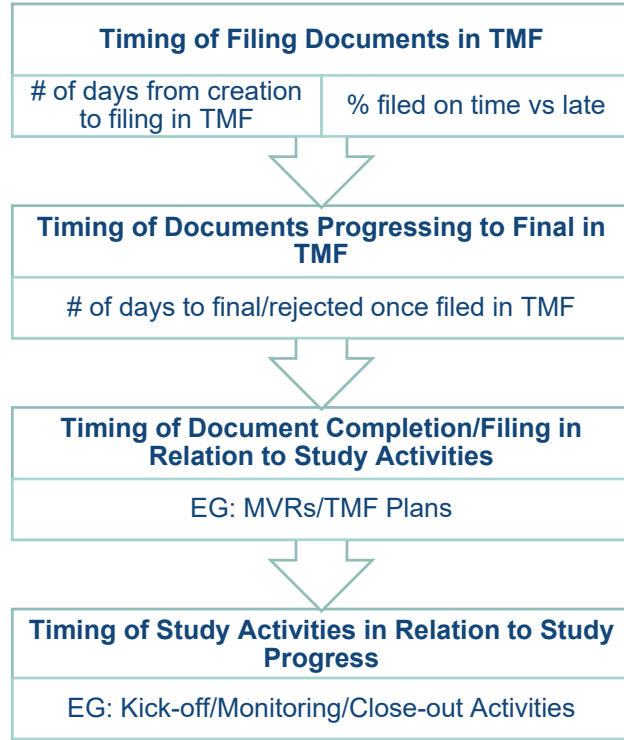
ARTIFACT a.

ARTIFACT	QueryCategory	Issue Summary	%
02.02.03 Informed Consent Form	Metadata error	Supporting Documentation	25%
05.02.07 Site Staff Qualification Supporting Information	Metadata error	Document Date	23%
05.03.03 Site Evidence of Training	Default	PDF correction	10%
05.04.03 Monitoring Visit Report	Visual quality error	Missing Information or Partial Document	18%
06.01.04 IP Shipment Documentation	Metadata error	Supporting Documentation	20%



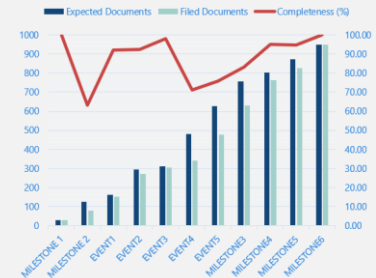
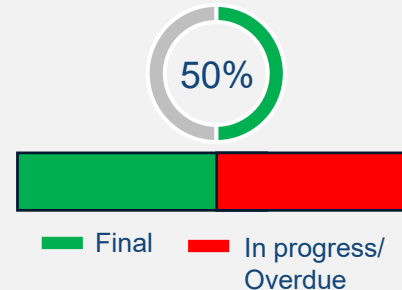
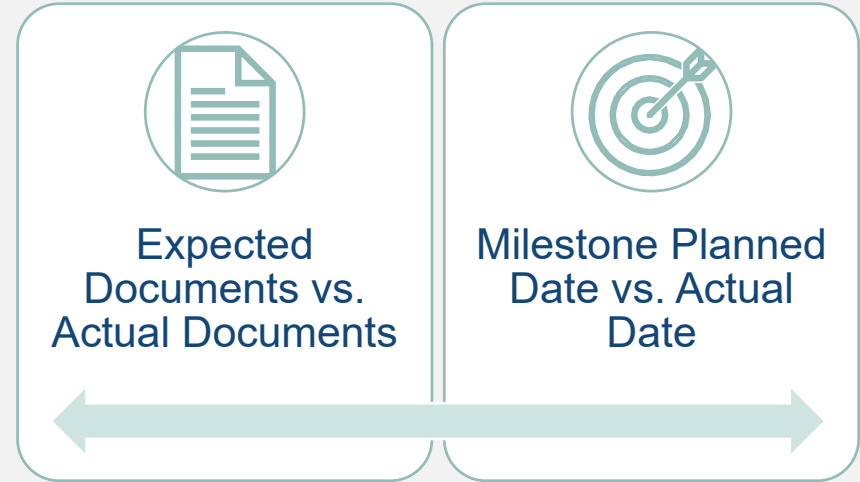
# Timeliness

Use pre-determined thresholds



# Completeness

Use pre-determined thresholds





# Turning Data into Trust: Storytelling That Drives Strategic Decisions



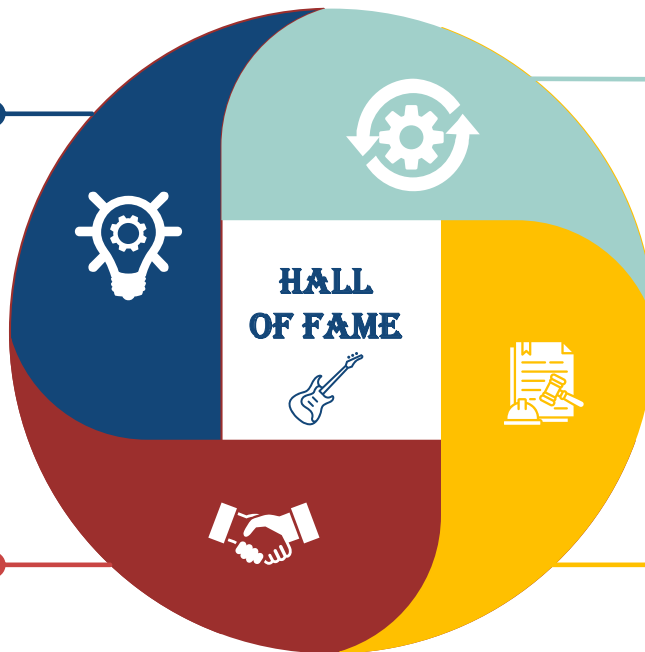
# How Data Tells the Story

## Informs Decisions

- Highlights trends, gaps and bottlenecks, enabling proactive decision making.
- Reveals areas of non-compliance or overdue tasks allowing for early intervention.
- Helps teams prioritize actions and allocate resources efficiently.

## Paints a Picture of Partnership

- Shared visibility fosters trust & alignment.
- Collaborative metrics highlight joint achievements & issues resolved through teamwork.
- Continuous improvement by tracking recurring issues & process delays can be used in joint retrospectives, showing a commitment to learn & grow together.
- Data also highlights success stories, reinforcing the value of partnership.



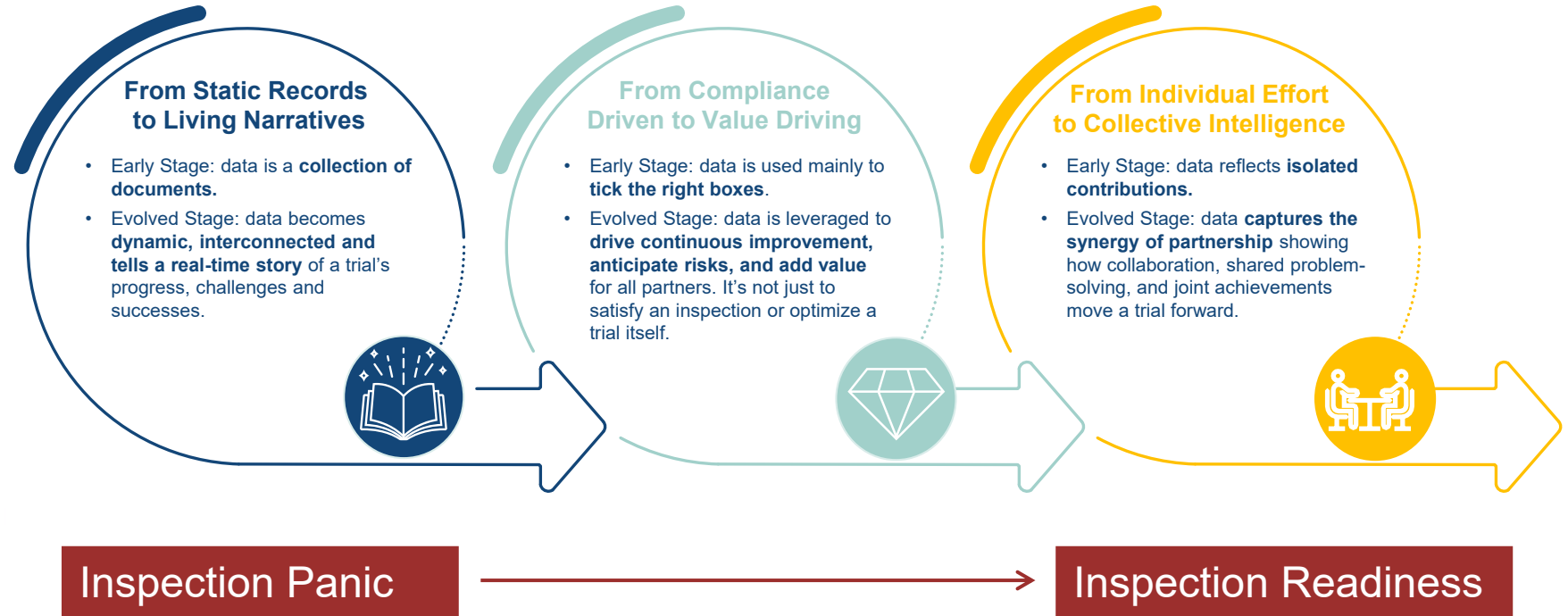
## Drives Compliance

- Comprehensive metadata ensures every document's lifecycle is traceable, supporting regulatory compliance.
- Data driven reminders and escalation workflows help ensure timely document collection, review and approval.
- Data validation rules can flag inconsistencies or missing information, reducing compliance risk.

## Supports Inspection Readiness

- Readiness indicators provide a clear, real-time view of TMF health.
- Organized data shows how each document supports the trial's conduct and oversight
- Data logs and reports demonstrate ongoing quality checks, issue resolution, and continuous improvement.

# Bringing the Evolution of TMF Data Full Circle



**Let's Do  
This  
Together:  
TMF  
Metrics  
Interest  
Survey**



# Country Music Hall of Fame's Kenny Chesney



- Artists were traditionally inducted due to their country roots and foundational influence
- Kenny was inducted in 2025 in the Modera Era Artist category
- Marked a shift in how the CMA evaluates artists
  - Chart Performance
  - Album sales
  - Touring Success
- Future outlook: Calling for greater transparency from CMA

Source: 5



**Thank You!**





# Sources

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