



2025

CDISC + TMF  
EUROPE INTERCHANGE

GENEVA

CONFERENCE & EXPO: 14-15 MAY | TRAININGS: 12, 13, 16 MAY

## Exploring the Role of TMF Metrics and KPIs in Trial Innovation - Is There a Purpose Beyond Inspection Readiness?

Presented by:  
Rob Jones – TMF Product Manager, Cencora

# Meet the Speakers



## Rob Jones

**Title:** TMF Product Manager

**Organization:** Cencora

In the industry for over 15 years, Rob has experience working across Sponsors, CROs and Vendors. After starting off in a white lab coat working with all manner of bodily fluids, he left the boring world of pipettes and entered the thrilling and exciting ride of documents, data, and records. Most recently Rob has been working at Cencora managing a team of 60 TMF experts working across a dozen sponsors before taking on ownership of the eTMF solution offered as well as supporting the other services offered by the TMF Practice Area.

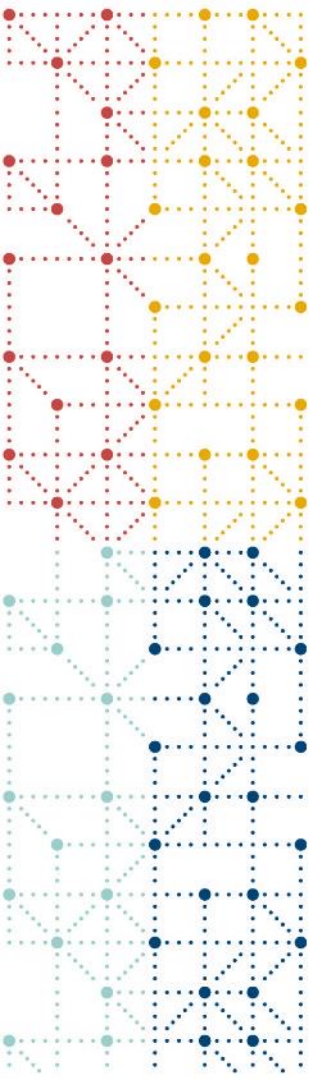
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# Agenda

1. The History of the Realm
2. Short Stories
  - 1.Preventing the Great Famine; a problem in the supply chain
  - 2.Disruption in the court; a traitor in the shadows
  - 3.Re-building the realm and working together
3. The Moral of the story

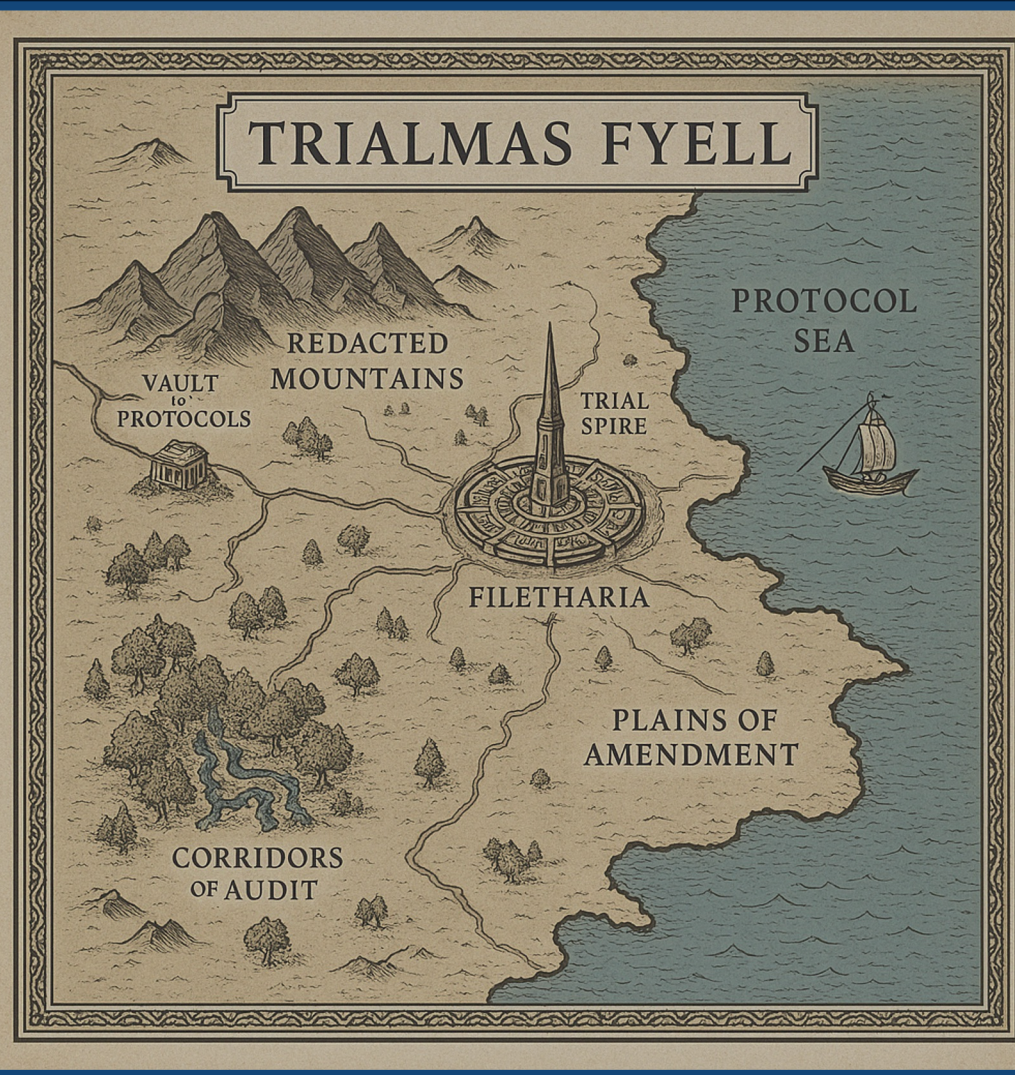


# The History of the Realm?



# At the dawn of time...

The realm of Trialmas Fyell was in disarray, infighting among the kingdoms brought them to the brink of war. But in the darkest time, even the smallest light can shine the brightest, three siblings rose to the peoples need and brought order from the chaos





# Three siblings stood tall...

The oldest brother, Tymel brought stability to the world ensuring no one would ever lose precious time again.

The middle brother, Qualciadiese took the realm and ensured quality and equality for all.

Finally, the youngest, the sister, most pure of the three, Comilla, completed the task and made the realm whole



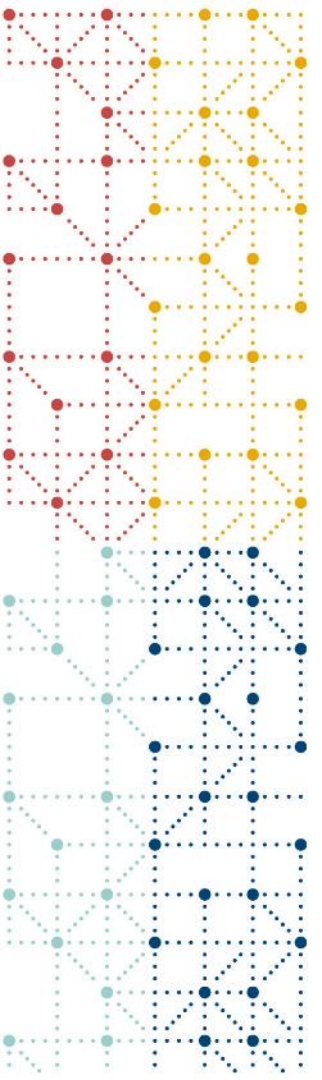


# Many years have passed...

The realm is now governed by the people, for the people. The Custodians of the Records oversee the country's eternal documentation, and the High Registrar leads with compassion. Their power passed down from Registrar to Registrar allowing them to recall any event in history with a single glance, ensuring the same mistakes are never made again.







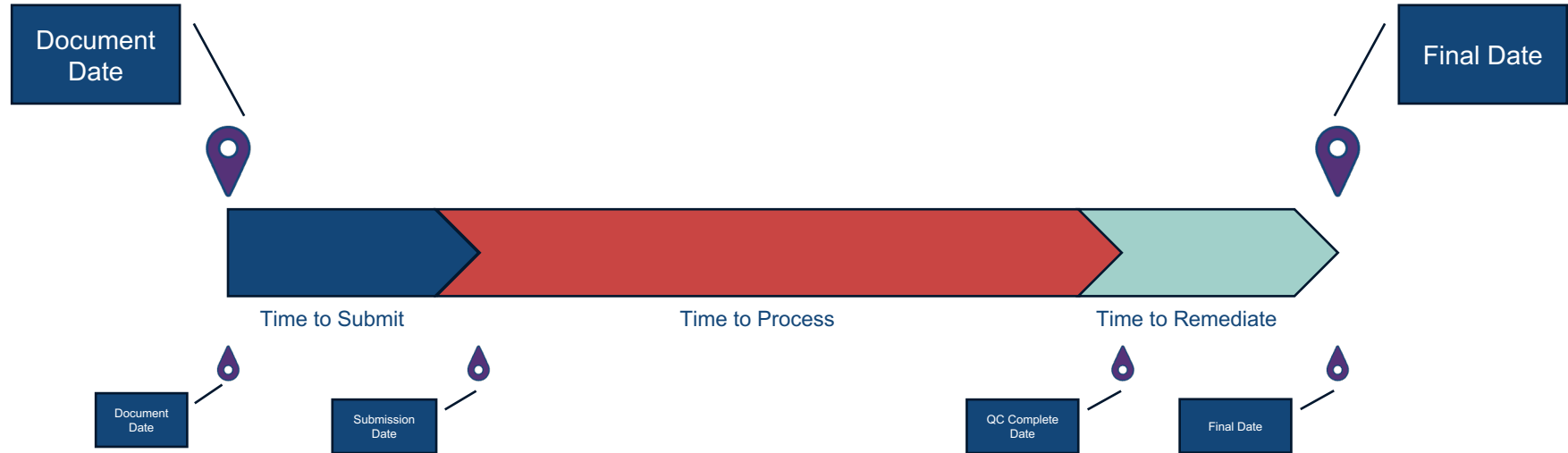
**What other stories can we learn from?**

# Preventing the Great Famine of 5403 AT, a problem in the supply chain



- Wheat was being prepared in the fields
- It was then transported to the mills for processing
- It was checked over
- Then turned to flour before going to the bakery
- Although bread was always available, it was only ever just in time

# Preventing the Great Famine of 5403 AT, a problem in the supply chain





# Preventing the Great Famine of 5403 AT, a problem in the supply chain



## The whole time is not the whole story

- Looking at each piece in isolation does have its benefits

## Even the smallest bottleneck can have a big impact

- Breaking the process down to each step can show where problems could occur

## Focus on the right thing, fix the right part

- Once you understand the problem you can fix it without wasting time on something that isn't even broken

By having more people review the wheat coming in on the wagons it could be processed quicker, and stock could be built up

# Disruption in the court; a traitor in the shadows



- Random mistakes were being made around the Castle
- Things were going missing, and people were heard scuttling in the halls after dark
- There was no clear lead, but people had their suspicions

# Disruption in the court; a traitor in the shadows

**PHLEX TFM** Dashboard Documents Approval Reports Study Mgmt

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Excused Placeholders  
Expiring Documents  
Milestones

Timeliness  
MV Report Timeliness by Company  
Representative Timeliness by Protocol  
Timeliness Heatmap by Country  
Timeliness Heatmap by Protocol  
Timeliness Ratio by Protocol  
TMF Timeliness

Duplicates  
Duplicate Documents  
Duplicates by Protocol

Queries  
Aged Queries at Client Review  
Aged Queries in Review  
Open Queries by Protocol  
Open Queries by Source  
Processing Quality Ratio by Protocol  
Queries Opened Over Time  
Time to Close Queries by Protocol

TMF Quality Review  
Artemis QC Review  
External QC Review

**User Audit**

User:  Date From:  Date To:  Company:  Protocol:

File Type:  Country:  Site-PI:  Zone:  Section:

Activity Type	Company	User	Date	Notes
Login Success	Test Parent Company	Robert Jones (rjones@phlexglobal.com)	24/Apr/2025 09:56 UTC	User 'rjones@phlexglobal.com' has successfully logged in, 'login type:SAML'
Login Success	Test Parent Company	Robert Jones (rjones@phlexglobal.com)	22/Apr/2025 12:04 UTC	User 'rjones@phlexglobal.com' has successfully logged in, 'login type:SAML'
Login Success	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Logout	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Document	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Document	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Login Success	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Logout	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Document	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Document	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Un Subscription	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Alert Sent	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
New Subscription	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Document	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		
Document	Test Parent Company	Robert Jones (rjones@phlexglobal.com)		

**PHLEX TFM** Dashboard Documents Approval Reports Study Mgmt

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**User Login**

Date From:  Date To:  User:  Company:

Company	Full Name	Email	Logins
Test Parent Company	AJS ADMIN	ASJADMIN@pavtest.com	10
Test Parent Company	AJS INDEX	AJSINDEX@pavtest.com	4
Test Parent Company	AJS Transmitter	AJSTransmitter@pavtest.com	12
Test Parent Company	Alex Shad	ashad@phlexglobal.com	120
Test Parent Company	Anke Huber	anke.huber@pharmalex.com	7
Test Parent Company	Client User 2	uat02@pavtest.com	2
Test Parent Company	Robert Jones	rjones@phlexglobal.com	6

Quality Review Count  
Quality Review Findings  
Quality Review Periodic Cycle  
Quality Review Periodic Cycle by Assignment  
Quality Review Query Ratio by Protocol  
Quality Review Status  
Quality Review Top Issues by Artifact  
Quality Review Top Issues by Site  
Quality Reviewed Documents

KPIs  
My Processing Issue Detail  
My Processing Issues  
My RFT Over Time  
Quality Ratio by Company  
Time to Close Queries by Company

eTransmittals  
eTransmittal Detail  
eTransmittal Summary

User Activity  
User Activity Summary  
User Audit  
User Inactivity  
User Login  
User Logins last 90 days  
User Profile  
User Profile History

Most systems will have a variation on above



# Disruption in the court; a traitor in the shadows



## What stands out

- Review audit trails regularly, this will help identify unusual activity

## Trends in the unusual

- Look for trends where there shouldn't be any

## Comparison is your friend

- Use others to compare against

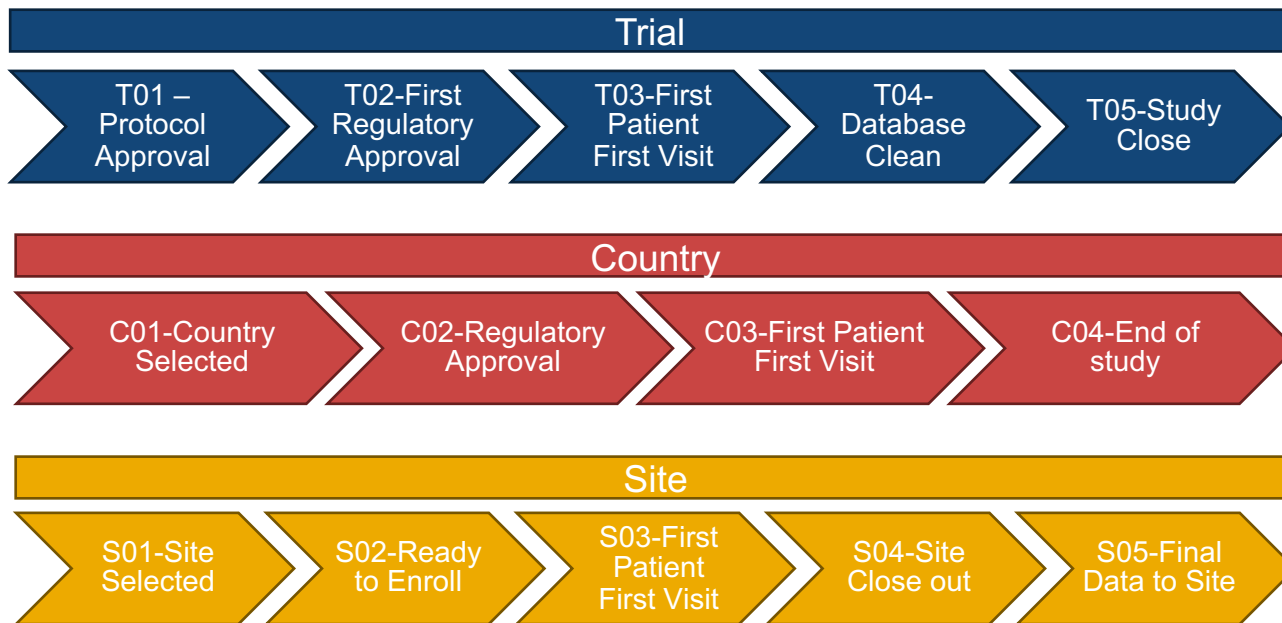
The traitor was found and exiled from the kingdom to live a life of poverty in the desolate wasteland

# Re-building the realm and working together



- Once peace was restored the kingdoms started to rebuild
- Such an effort required lots of people and skills
- They were not all needed at the same time
- A plan was needed to be as efficient as possible and respect the time of all involved

# Re-building the realm and working together



- Using Milestones, you could help plan the study and resources
- Certain functions play larger parts at certain times
- As the study comes to a close, resources can move to new work



# Re-building the realm and working together



## Utilise what you already have

- The TMF is a great tool and provides more benefit than it is often used for

## Everyone has a part to play

- There are no major or minor roles in a clinical trial, working together is the only way to success

## No one likes surprises

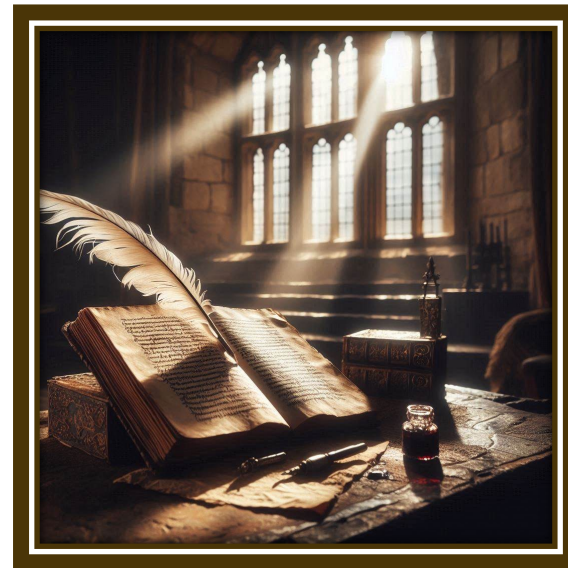
- Sharing changes early, be it good or bad, is always encouraged

By working together each Kingdom was restored and the people could look to better times ahead

# The moral of the story



TMF Health is more important than ever and will always be the main story...



... but it is not the only story. We can learn a lot about continuous improvement, dealing with risks and collaboration without much more effort



They All Lived Happily, Ever After

The End?



# Thank You



**cencora**

Rob Jones

**Title:** TMF Product Manager

**Organization:** Cencora

