



2024 CDISC + TMF
EUROPE INTERCHANGE

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Improving Your TMF Culture: Winning Hearts and Minds

Presented by Chris Jones, Head CDM Business Operations, Clinical Document Governance & Management, Novartis



Meet the Speaker

Chris Jones

Title: Head, Clinical Document Management Business Operations

Organization: Novartis

Head, Clinical Document Management Business Operations at Novartis since August 2021, based in the UK.

Part of the team accountable for clinical document management and TMF at Novartis - rives the implementation of the clinical document management strategy to deliver on immediate needs and medium-long term roadmap, in alignment with the evolving portfolio, operating model and overall pipeline delivery strategy.

Prior to joining Novartis had a long career with SmithKline Beecham & GlaxoSmithKline (now GSK) in records management, archiving and clinical document management.



Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*



Agenda

1. About TMF Culture
2. Reasons for poorly managed TMFs
3. Approaches that could work (and others that may not)
4. When is the work on TMF culture finished?



About TMF Culture

What is your organization's culture?



Inspired

Engage our people. Strive for patients. Live our purpose.



Curious

Learn. Be open. Be self-aware.



Unbossed

Create clarity. Serve others. Own your actions.



Integrity

Be honest. Have courage. Do what is right.

Source: <https://www.novartis.com/about/people-and-culture>



What does a good TMF culture look like?

Individuals/teams know & understand their accountabilities

There is strong collaboration across teams/individuals

TMF is embedded into ways of working, not treated as an add on

Strong TMF health is achieved the right way, successes are celebrated, issues are tackled

Ways of working are inspection ready, not inspection driven

TMF enables better clinical trials

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Inspired



Reasons for poorly managed TMFs

Some reasons (excuses) for poorly managed TMFs

My other study activities are more important

TMF doesn't apply to me, I am not part of clinical

My study isn't being inspected

I know I need to do it, but I don't have the time

TMF is not in my objectives

I find the system / processes too complex to use

I don't know how to do it

My job is to make patients better, not do filing



Approaches that could work (and others that may not)

What is not likely to work well

- A bottom-up approach
- Not realising the *why* isn't understood
- Appealing to people's better nature
- Focussing on inspection readiness



What can work well

- Having a simple vision/message
 - What is your TMF simple strapline
- Refreshing on fundamentals
 - Good document management; importance of TMF to successful clinical trials
- Investing time on stakeholder mapping
 - Keep it up to date – organizations change!
- Identifying & partnering with champions/influencers
 - Those passionate about TMF who understand their functions, countries, teams
- Engaging, listening and respond
 - With all levels of the organization
 - Formally or informally



What can work well (continued)

- Setting TMF objectives for senior leaders
 - Cascade the objectives to individuals in their teams
- Tracking & reporting progress or otherwise
- Removing obstacles/easing the burden
 - Process & system improvement, training, user support
- Changing the narrative
 - The art of the possible – share successes
 - TMF is an enabler for better clinical trials





When is the work on TMF culture finished?

It's a never ending story....



Change is constant

Technology change
Processes change
People change
Organisations change



Continual need to
monitor & adjust



Thank You!

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