2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Rethinking TMF Quality: Moving Beyond Document Timeliness

Nina Louise Arberg, Senior Clinical Document Manager, Ferring Pharmaceuticals

Chris Jones, Head of CDM Business Operations, Novartis

Franciska Darmer, Global Head of Clinical, Base Life Science

Torsten Stemmler, Head of Inspection Unit, BfArM

Speakers

Nina brings 8 years of experience in biopharma having worked with both paper and electronic Trial Master Files, supporting global clinical trials.

Specializing in oversight of outsourced TMF activities, quality oversight, inspection readiness, and ensuring compliance with ICH-GCP and regulatory expectations.

Nina Louise Arberg

Senior Clinical Document Manager

Ferring Pharmaceuticals

Speakers

A committed, driven, pragmatic leader with 30+ years of experience in pharmaceutical records management and archiving.

For the past 10 years have specialized in Clinical Document Management.

Focussed on compliance, process improvement, risk-based decision making and developing team capabilities.

Chris Jones

Head, Clinical Document Management Business Operations

Novartis

Speakers

Franciska brings over 25 years of experience in the life science industry, having worked with pharma, technology vendors and global IT services teams.

Specialized in guiding companies through digital transformation across R&D and with strong focus on eTMF management acceleration and performance though technology enablement.

Franciska Darmer

Global Head of Clinical

BASE Life Science

Speakers

Dr. Torsten Stemmler earned his PhD in Biology (Neurobiology and Psychophysics) from the University of Bremen, Germany, in 2011. Following his doctoral studies, he pursued postdoctoral research at RWTH Aachen, focusing on visual perception.

His career took a dynamic turn when he retrained as a Data Manager, developing database solutions at the University Hospital Aachen.

In 2017, he brought his expertise to the Federal Institute for Drugs and Medical Devices, where he serves as a GCP Inspector, ensuring compliance with Good Clinical Practice standards.

Dr Torsten Stemmler

Head of GCP Inspection Unit

Federal Institute for Drugs and Medical Devices (BfArM)

Agenda

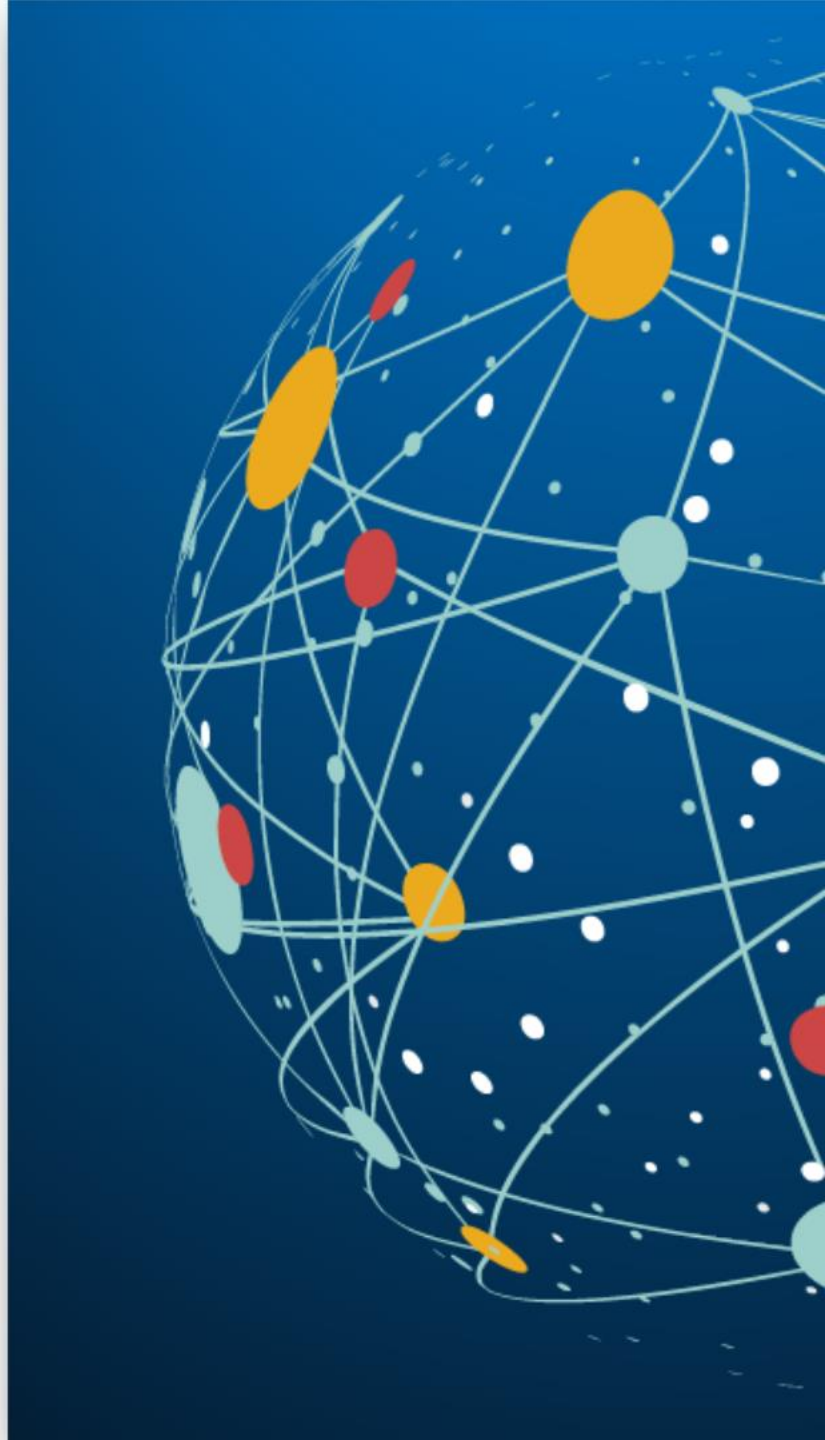
1. TMF Document Timeliness: Is It Still a Valid Quality Measure?

2. Shifting the Focus: From Document Timeliness to Milestone Timeliness

TMF Document Timeliness:
Is It Still a Valid Quality Measure?

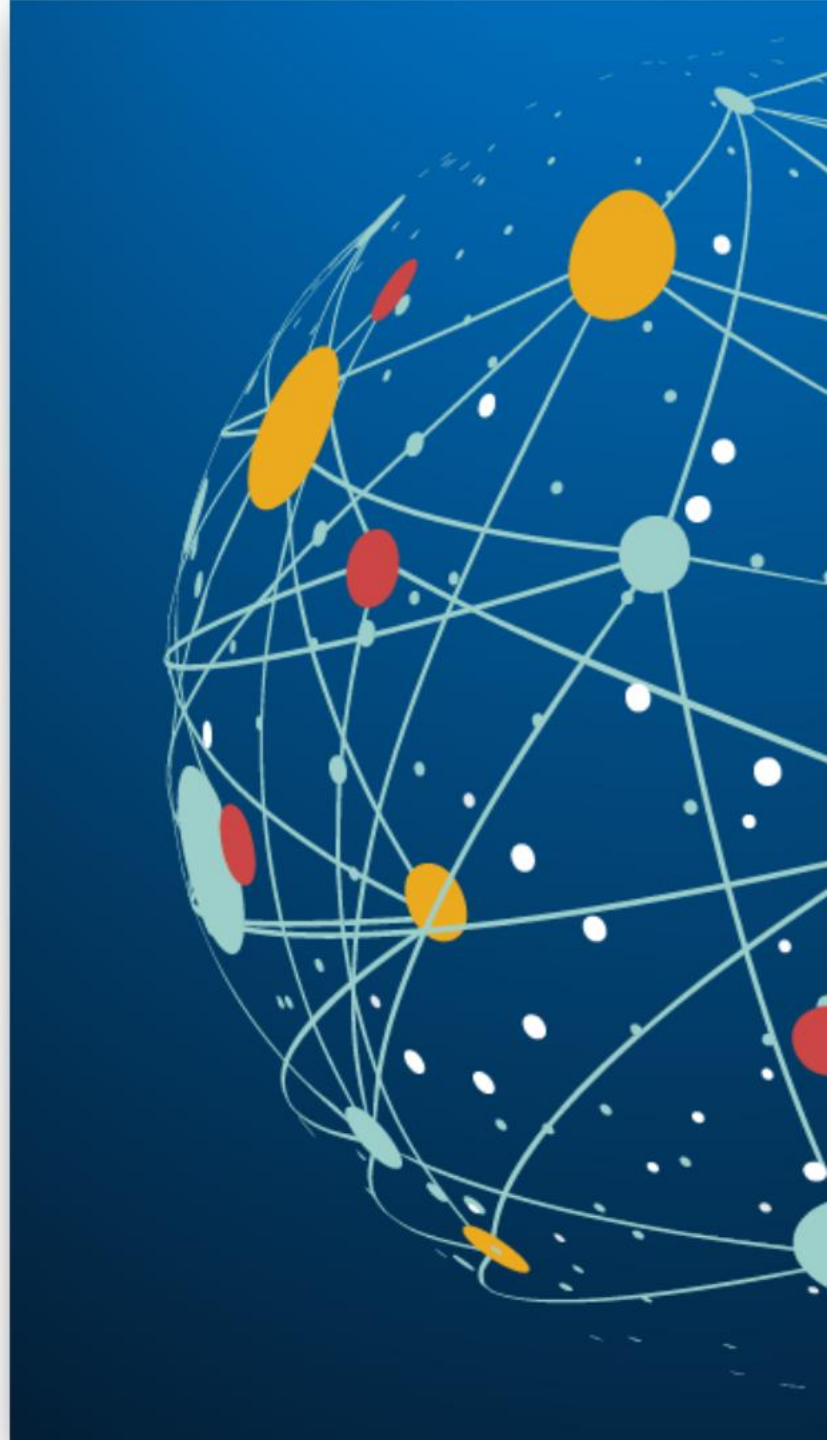
- Does document timeliness add real value as a quality indicator?

- Does document timeliness still matter?



Poll

Is document timeliness addressed in your company's SOPs?



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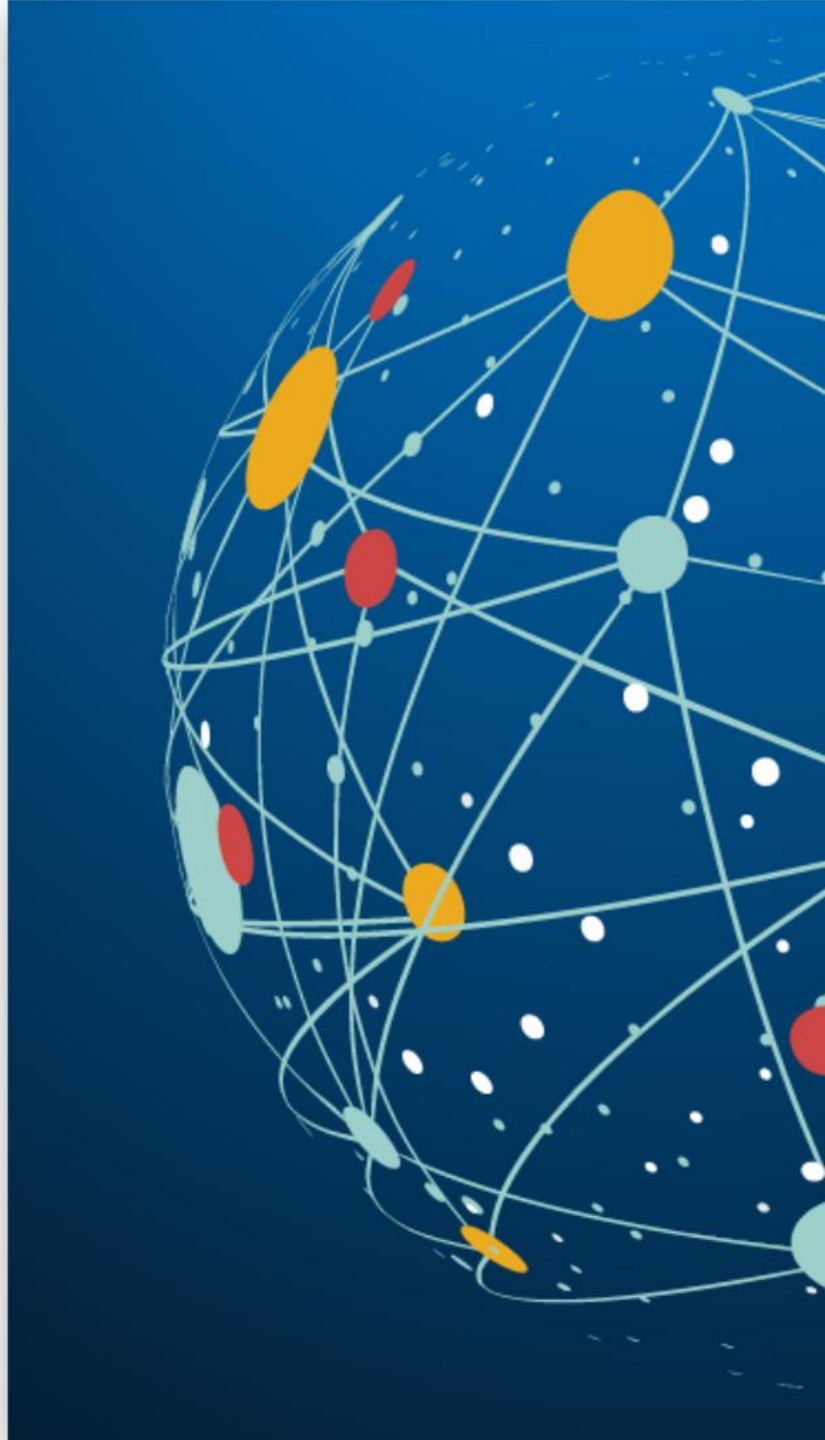
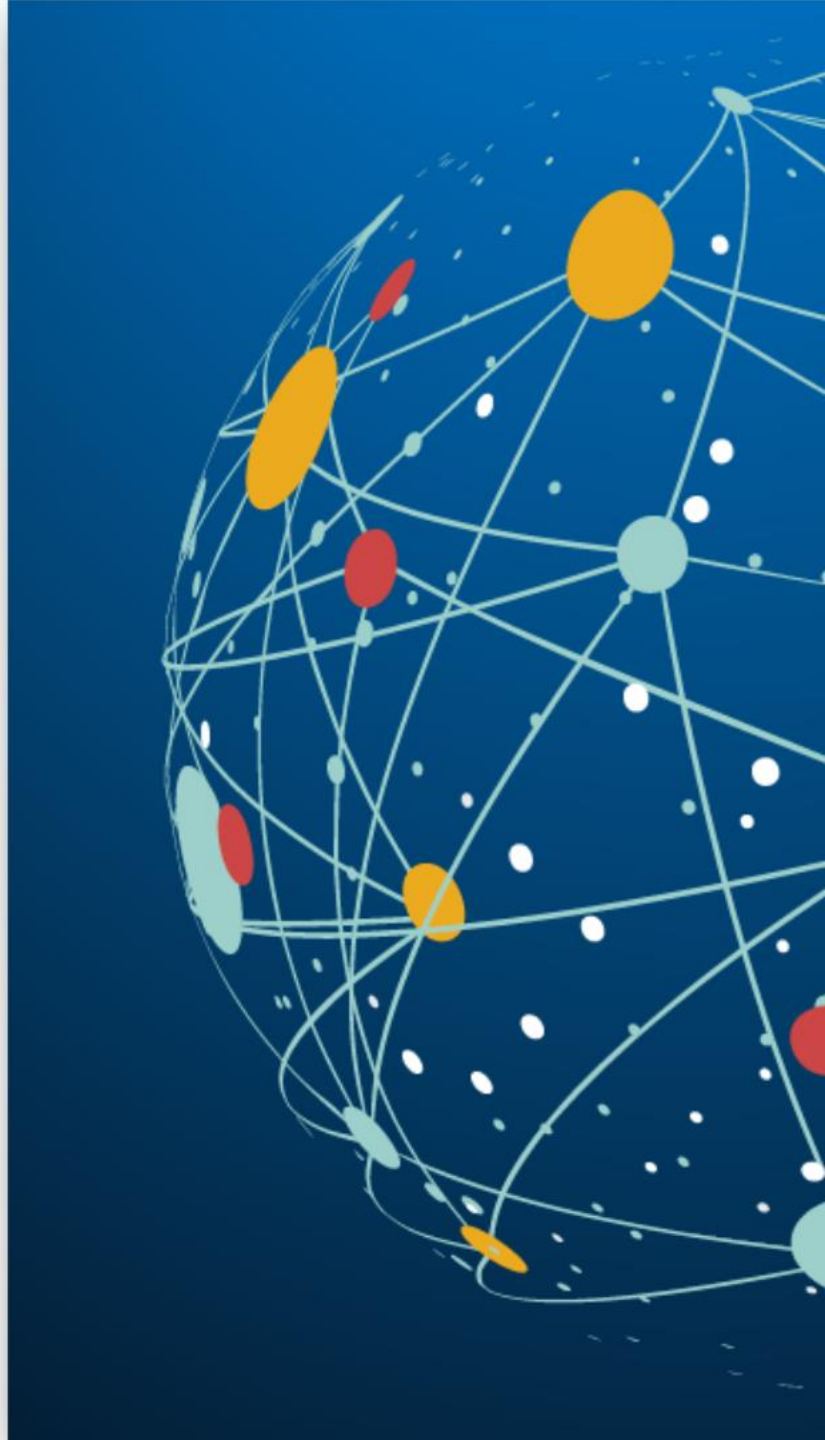
Is document timeliness used as a TMF Quality indicator in your company?



Shifting the Focus: From Document Timeliness to Milestone Timeliness

- Does milestone timeliness better reflect TMF Quality?
- What should be considered when using milestone timeliness as a TMF quality indicator?



Questions?

Thank You!