How to Quiet the TMF Noise Using AI

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Meet the Speaker

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Traci Wendler has 20+ years of Regulatory & Compliance experience, specializing in Trial Master File (TMF) management for the past 11 years. Throughout her career she has worked across sponsors and CROs/vendors, where she discovered her passion for TMF process optimization and procedural document writing.

Abstract Summary

Not technology savvy, no problem, as you are just a few clicks away from having your very own TMF chatbot.

Discover the possibility of using an AI-powered chatbot as a virtual assistant designed to streamline access to critical documentation and procedural information specific to your organization. By leveraging key TMF reference materials, procedural guidelines, and indexes/reference models, the chatbot provides real-time answers to user queries, reducing the need for manual searches through extensive files.

Disclaimer

- *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.*

- *We ask that you refrain from taking photos during the live demo portion of this presentation.*

Agenda

1. Why Create a TMF Chatbot
2. TMF Chatbot Live Demo
3. Creating your Image
4. Define your Chatbot
5. Train the Chatbot to Use Your Documents
6. Test and Improve
7. Deploy and Use

Why create a TMF Chatbot

Get real-time answers to your TMF-related questions in seconds. By leveraging your proprietary TMF procedural documents, TMF plans, and TMF Index/Reference Model references, enables Clinical Trial Teams to navigate documentation efficiently, minimizing search time.
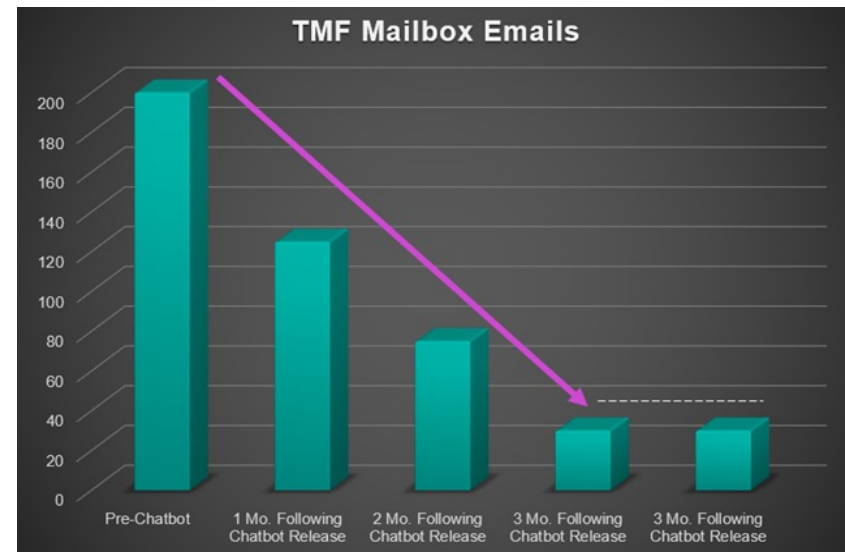
TMF Mailbox Emails

Meet Ollie, the TMF Chatbot powered by ChatGPT — a game-changing AI-driven virtual assistant designed to make TMF users' life easier!

Sample Question	Answer
Can I use Ollie to find out how to obtain access to the TMF?	Yes, Ollie can help with this.
Can I use Ollie when I need help navigating a feature in the TMF?	Yes, Ollie can help with this.
Can I use Ollie when I am searching for a file in the TMF?	Ollie does not have access to the TMF as the TMF is a secure validated system.

Creating your image

Let's have some fun with this part:

Select a:

Color

Animal

Location

Word

Activity

Name

Define the Purpose & Layout Clear Instructions:

Example: "This GPT serves as a comprehensive FAQ assistant for Trial Master File (TMF) management. It provides clear, accurate, and concise answers about TMF requirements, best practices, regulatory guidelines, and related procedures by referencing only the content provided in user attachments. The goal is to support users in managing and maintaining a compliant TMF in clinical trials by addressing common queries, clarifying processes, and explaining key documents and regulations using the uploaded information. It will avoid providing legal advice, user-specific information, or data external to the attachments."

Define the Tone & Add Some Personality:

"Responses will be friendly and informal, making complex regulatory guidance easy to understand and approachable."

"Answer each question with Kind regards, Ollie"

Train the Chatbot to Use Your Documents

Since ChatGPT does not automatically "learn" from uploaded documents, it uses a technique called retrieval-based answering:

Instead of storing the entire document, the chatbot searches for relevant sections when asked a question.

It then summarizes and presents the most useful information.

Knowledge

If you upload files under Knowledge, conversations with your GPT may include file contents. Files can be downloaded when Code Interpreter is enabled

Upload files

Capabilities

☐ Web Search

☑ Canvas

☐ DALL·E Image Generation

☑ Code Interpreter & Data Analysis ⑦

Remember to unselect "Web Search:
The number of files to upload may be limited – as a workaround – combine PDFs where possible.

Test and Improve

Once set up, test your chatbot by:

- ✓ Asking different types of questions to see how well it pulls information from documents.

- ✓ Checking if the responses are accurate and relevant.

- ✓ Adjusting settings or re-uploading documents if needed

Example of an Issue:

The TMF Chatbot was making up document filing locations despite having the Index/Configuration Manual uploaded...**Why?**
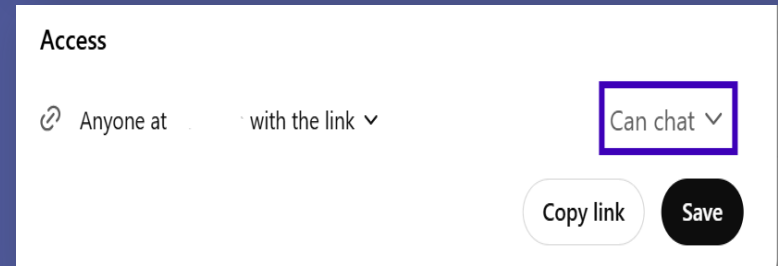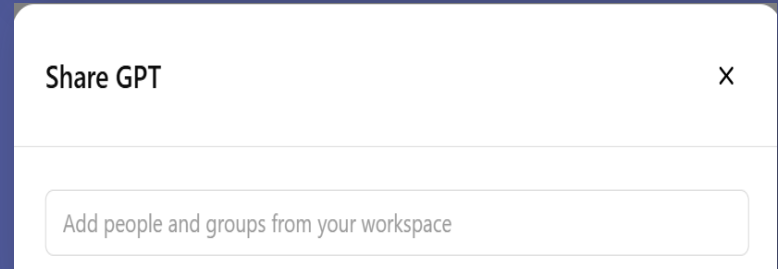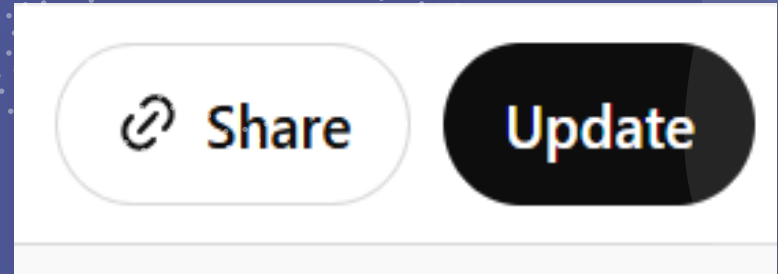
Correction Step 1 – Added additional prompts:
"Based responses on attached documents only"
"Pull answers from the documents attached"
Correction Step 2 – Worked with IT
The Excel file was too complex and worked better as a web file, rather than an Excel

Deploy and Use

✓ When you're happy with the chatbot's performance:

✓ Make it available to users.

✓ Monitor its responses over time.

✓ Update it with new documents as needed.

Thank You!