



**2025**

**CDISC + TMF  
EUROPE INTERCHANGE**

**GENEVA**

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

# **How to Leverage Next-Gen Tools to Optimize TMF Processing**

**May 14, 2025**

Aaron Grant, Head of Innovation, Just in Time, GCP  
Carol Radwanski, Director, TMF Services, Just in Time, GCP

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# Meet the Speakers

## Aaron Grant

**Title:** Head of Innovation

**Organization:** Just in Time GCP

Aaron Grant is the Head of Innovation at Just in Time GCP, leading the integration of advanced technologies to enhance clinical operations and ensure GCP compliance. With over 20 years of experience in regulatory and clinical research technology, he is focused on delivering practical, usable solutions that delight users and improve business practices. Aaron is a regular contributor to the CDISC TMF Reference Model helping shape the technical direction of the TMF industry including EMS, DDF and V4.

## Carol Radwanski

**Title:** Director, TMF Services

**Organization:** Just in Time, GCP

Carol brings over nine years of specialized experience in Trial Master File (TMF) management. Her career in the clinical research industry began with Phase 1 clinical trials, laying a strong foundation in regulatory documentation and compliance. Most recently her focus has been on supporting TMF oversight across multiple portfolios and therapeutic areas, ensuring the completeness, accuracy, and ongoing inspection-readiness of essential clinical trial documentation. In her current role, Carol is responsible for a wide range of activities, including quality control (QC) oversight, TMF migrations, audit preparation and support, and team training. She also plays a key role in staff management and development, fostering growth within her team while implementing and refining standardized processes to enhance TMF consistency and compliance across studies.

# Agenda

**Background**

**Idea Generation**

**Pilot**

**Rollout**

**Feedback/Metrics**

**Lessons Learned**



# Background of QC Process

## QC Process at JiT

- **Upload, classify, and process documents** through the QC workflow, ensuring consistent application of procedures.
- A **high standard of quality** is upheld throughout the project lifecycle, maintaining compliance with ALCOA+ principles to ensure data integrity and inspection readiness.
- Multiple guidance documents to reference in order to perform their daily responsibilities making standardization a challenge.

## Challenges

- Multiple areas of reference
- Same issues over the years /feedback across all clients.



# Background on Technology Landscape

## Just in Time GCP constraints:

- We are not a software company
- Avoid Validation – Person in the loop
- No client data – contracts were not in place
- Quick Wins
- Ideas are always around, but how do we move them forward?

## Generative AI Assistant provides new opportunities

- Good at understanding rules, documents, requirements
- Multiple client filing rules creates confusion
- Enhance processing – lower training time, reduce errors, increase speed, increase employee satisfaction





# Idea Generation

## Why did we choose this project?

- High volume environment that allows for a substantial sampling of documents.
  - Centralized point for information, resources, or materials
  - Quick implementation without compromising quality or compliance

## Project Vision

- Single source
  - QIs-can it standardize the language
  - Dating conventions
  - Multiple Monitors; Can that be reduced?
  - Alexa for Rules; Can it be voice activated?



# Idea Development

## Merging both worlds together

- **Don't discount anything**; throw ideas out as it may be easier than you think
- Picklist generated to speed up answer generation
- Sidebar application experimented with for single screen visualization
- “Alexa” functionality. Spoken Input identified as useful for non- typist

## Implementation

- **Rapid prototyping** for quick feedback
- **Close communication** to implement ideas
- **Identify Clear Owners** within the organization
- **Ensure Executive Buy-In** and checkin often

### Finan

#### Committee Member Financial Disclosure Form

Zone: 01. Trial Management  
Section: 01.03 Trial Committee  
Artifact #: 01.03.05  
Artifact: Committee Member Financial Disclosure Form

#### Financial Disclosure Summary

Zone: 02. Central Trial Documents  
Section: 02.01 Product and Trial Documentation  
Artifact #: 02.01.05  
Artifact: Financial Disclosure Summary

#### Financial Disclosure Form



# Pilot

## Pilot-first approach

- Initial implementation was limited to a small, controlled group to test feasibility, gather feedback, and make early improvements before a broader rollout

## Participant Selection Criteria

- **Open-minded** and receptive to new technology
- **Comfortable with change** and eager to explore new ways of working
- **Natural communicators** who could advocate for the initiative
- **Flexible and collaborative**—willing to help teammates and answer questions
- **Proactive in surfacing issues** and suggesting improvements
- **Leaders/Respected** from larger group (for later)



# Pilot

## Improve Reliability

## How to rollout and check in (3-month test)

- Lots of touchpoints
- Lots of hands on
- Lots of sharing

## Quick updates with clear communication

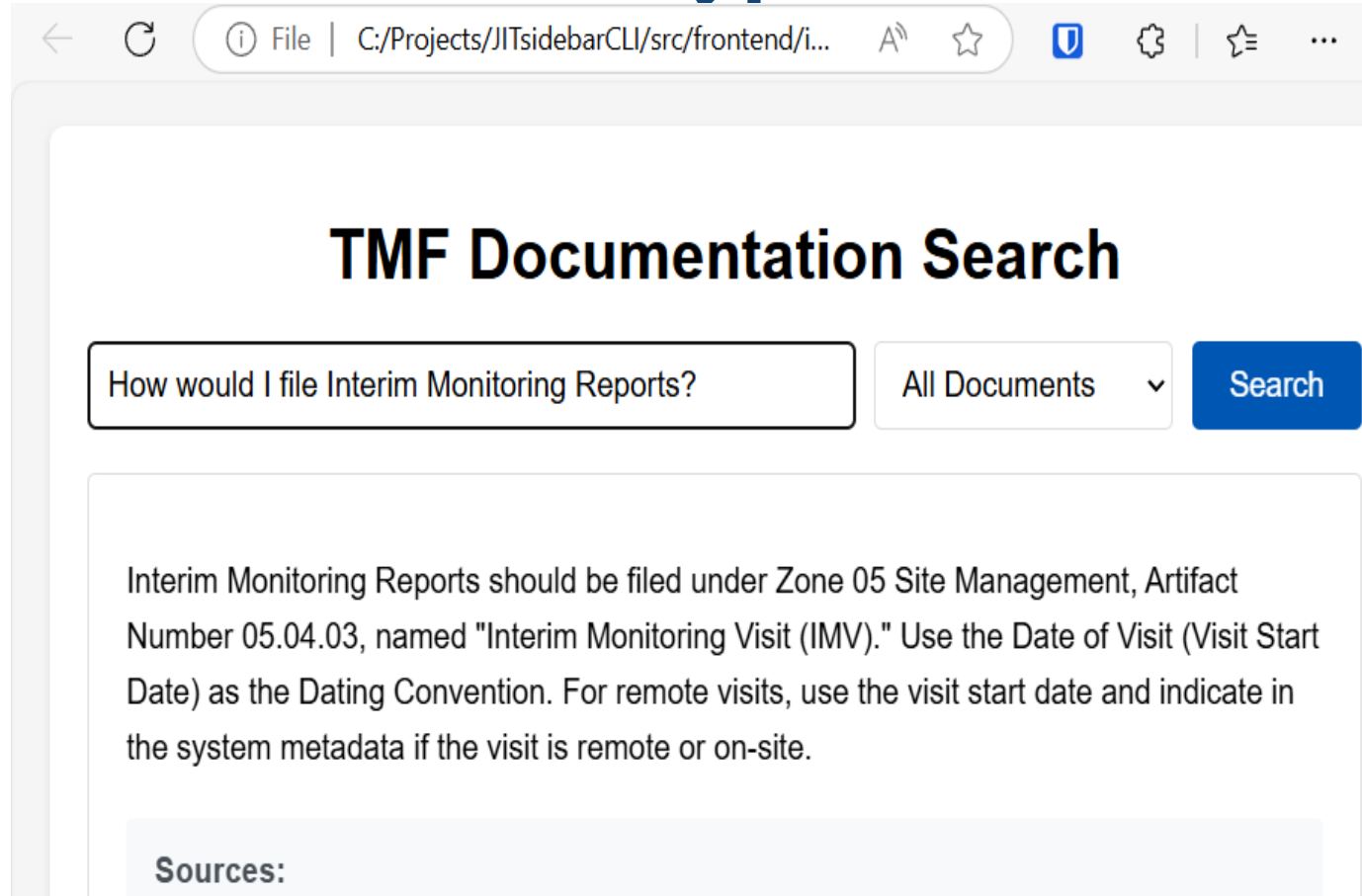
- Updates to guidance documents
- Updates to sidebar

## Learning the realities/limitations on new technology

- Really liked to make up record locations that don't exist



# Evolution of a Prototype



The screenshot shows a web browser window with the address bar displaying 'C:/Projects/JITsidebarCLI/src/frontend/i...'. The page title is 'TMF Documentation Search'. Below the title is a search interface with a text input field containing 'How would I file Interim Monitoring Reports?', a dropdown menu set to 'All Documents', and a blue 'Search' button. Below the search bar is a text area containing the following text: 'Interim Monitoring Reports should be filed under Zone 05 Site Management, Artifact Number 05.04.03, named "Interim Monitoring Visit (IMV)." Use the Date of Visit (Visit Start Date) as the Dating Convention. For remote visits, use the visit start date and indicate in the system metadata if the visit is remote or on-site.' At the bottom of the page is a light blue box with the label 'Sources:'.

## TMF Documentation Search

How would I file Interim Monitoring Reports?

All Documents ▾

Search

Interim Monitoring Reports should be filed under Zone 05 Site Management, Artifact Number 05.04.03, named "Interim Monitoring Visit (IMV)." Use the Date of Visit (Visit Start Date) as the Dating Convention. For remote visits, use the visit start date and indicate in the system metadata if the visit is remote or on-site.

Sources:



# Evolution of a Prototype

1 JiT Service Enhancer

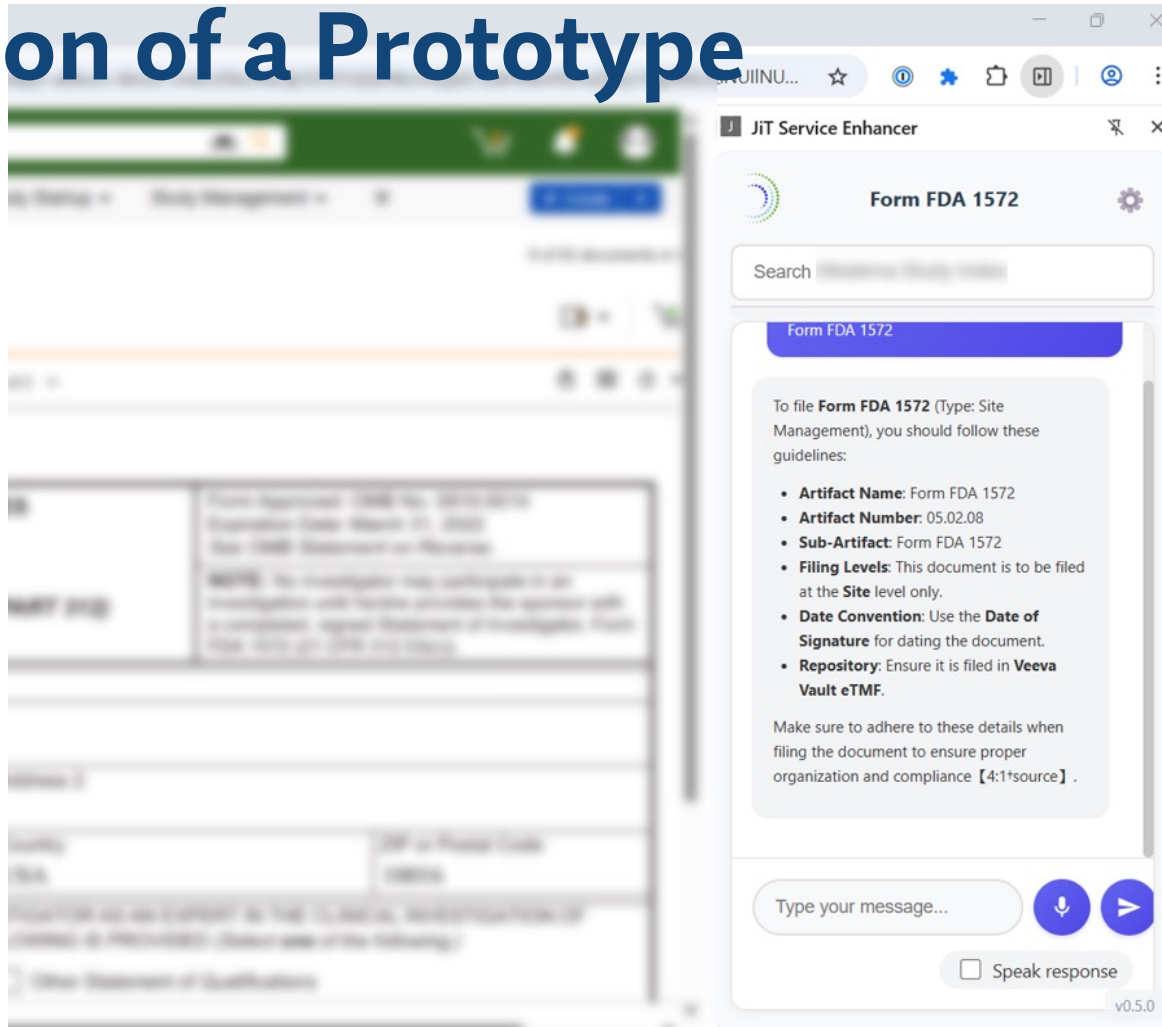


Login

Tell me about Interim Monitoring Visit Reports

Interim monitoring visit reports are used in clinical research to assess the progress of a study and ensure compliance with protocol and regulations. These reports are typically conducted by monitors or auditors who visit the study site and review various aspects of the research, including data collection, informed consent procedures, participant safety, and adherence to the study protocol. During an interim monitoring visit, the monitor will inspect study records, interview study staff, and observe study procedures to identify any potential issues or deviations from the protocol. The monitor will then document their findings in a report, which may include recommendations for corrective actions or improvements. Interim monitoring visit reports are important for ensuring the integrity and quality of clinical research studies. By conducting regular monitoring visits, sponsors and regulatory authorities can identify and

# Evolution of a Prototype



# Rollout

## Change Management

- **Encourage use rather than enforce it.** Focus on building buy-in
- **Leverage Change Agents** These early adopters were expected not only to test the system but also to act as champions, helping to drive adoption, share learnings, and smooth the transition for the wider team.
- Clearly communicate that the initiative is ***not* a threat to job security**
- Engage with those who have negative connotations about it. **Listen to their concerns and offer reassurances** through communication
- Acknowledge that adopting this process may **initially slow productivity** and there **won't be consequences** for a temporary drop in performance metrics.
- Training when new updates to guidance and rules





# Rollout

## Training

- Develop Materials
- Multiple Groups

## “Hypercare” Support

- Provide intensive early-stage support during rollout
- More problems will be found!
- Collect qualitative feedback
- Collect information of the next features

## Metri-gistics

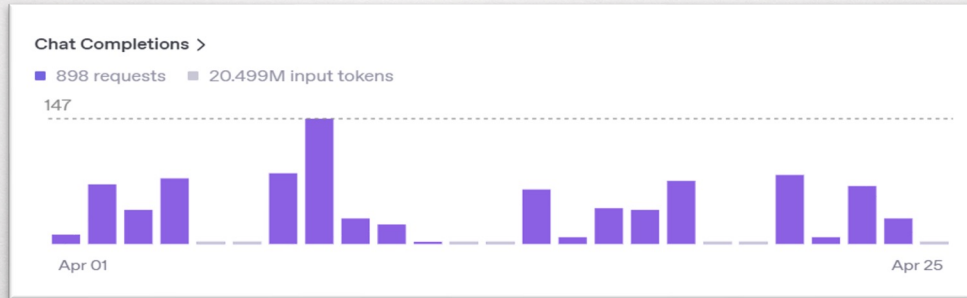
- Who is responsible
- When will you look



# Metrics and Feedback

## Usage Data

Timeliness and Quality metrics will continue to be collected on a quarterly basis to evaluate QC sidebar efficiency



"Whenever I searched, it has given correct information"

"I do find it to be useful; Can I use this on my other client?"

"Tells me what I need to know" If it could tell us where a record needed to be classified that would really help, but then I probably would not be needed."

"Outside of efficiency, on a more personal note – **generative AI in general has an astronomically negative impact on the environment** and I don't find that the benefit of this tool in our process outweighs the negative impact that our company using this function on a large scale would have. For all these reasons I just don't see myself using this tool regularly at this time."

# Lessons Learned

## Keep Going!

- Go back to Phase 1 again
- Constantly evolving

## Mistakes will be made ... that's ok.

- Just have processes to collect and mitigate

## Start small

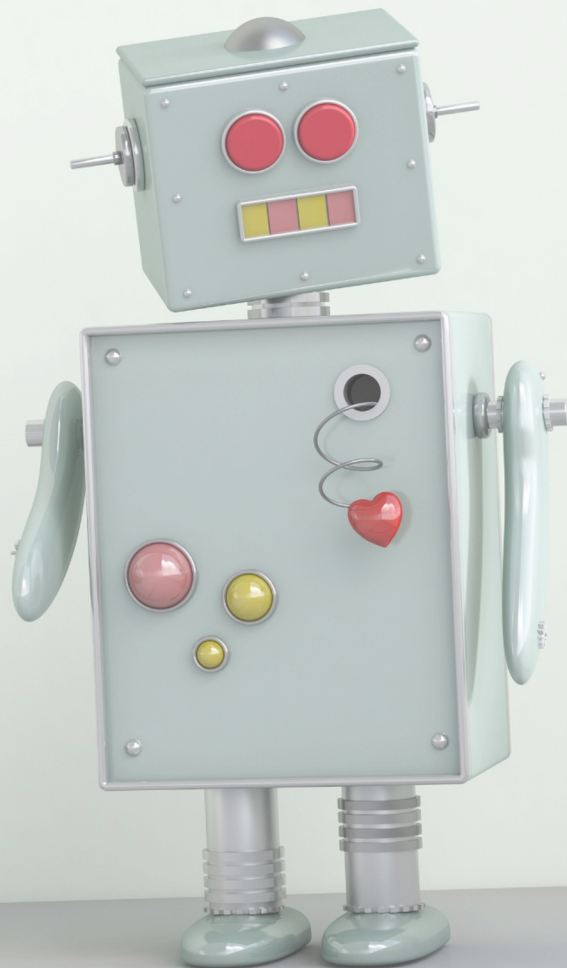
- Pick small projects that allow for exploration and learning
- Use them as opportunities to experiment with technology

## Messaging

- Avoid creating fear, but instead create excitement

## Collaboration

- Pair idea people with execution people
- Innovation is a team effort





Questions?

