



2023 CDISC TMF INTERCHANGE

BALTIMORE | 28-29 SEPTEMBER



Harnessing the Power of Your TMF Index

Presented by Laura Wiggins, Project Manager, Just in Time GCP



Meet the Speaker

Laura Wiggins, MBA

Title: Project Manager

Organization: Just in Time GCP

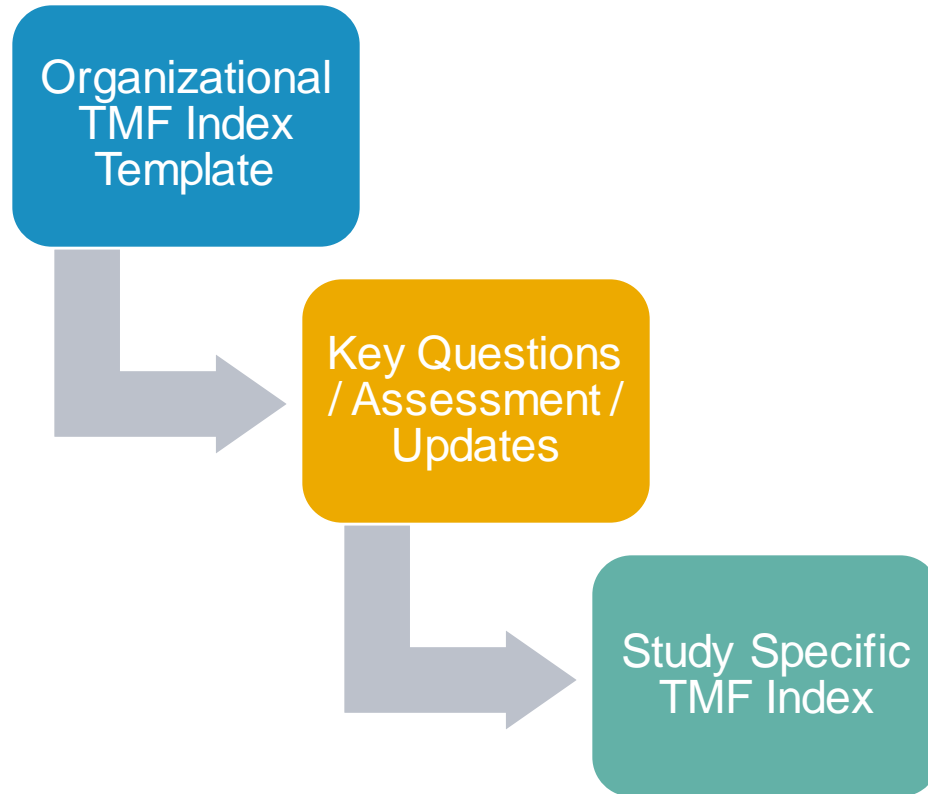
Laura has over 20 years of experience in Clinical Research and Marketing. Within the Phase 1 unit and CRO space, she was responsible for participant recruitment, media planning and buying, outreach activities, business development and medical writing.

Currently at Just in Time GCP, Laura manages projects which analyze, develop and implement processes that support business use of electronic clinical systems to ensure TMF quality and completeness.

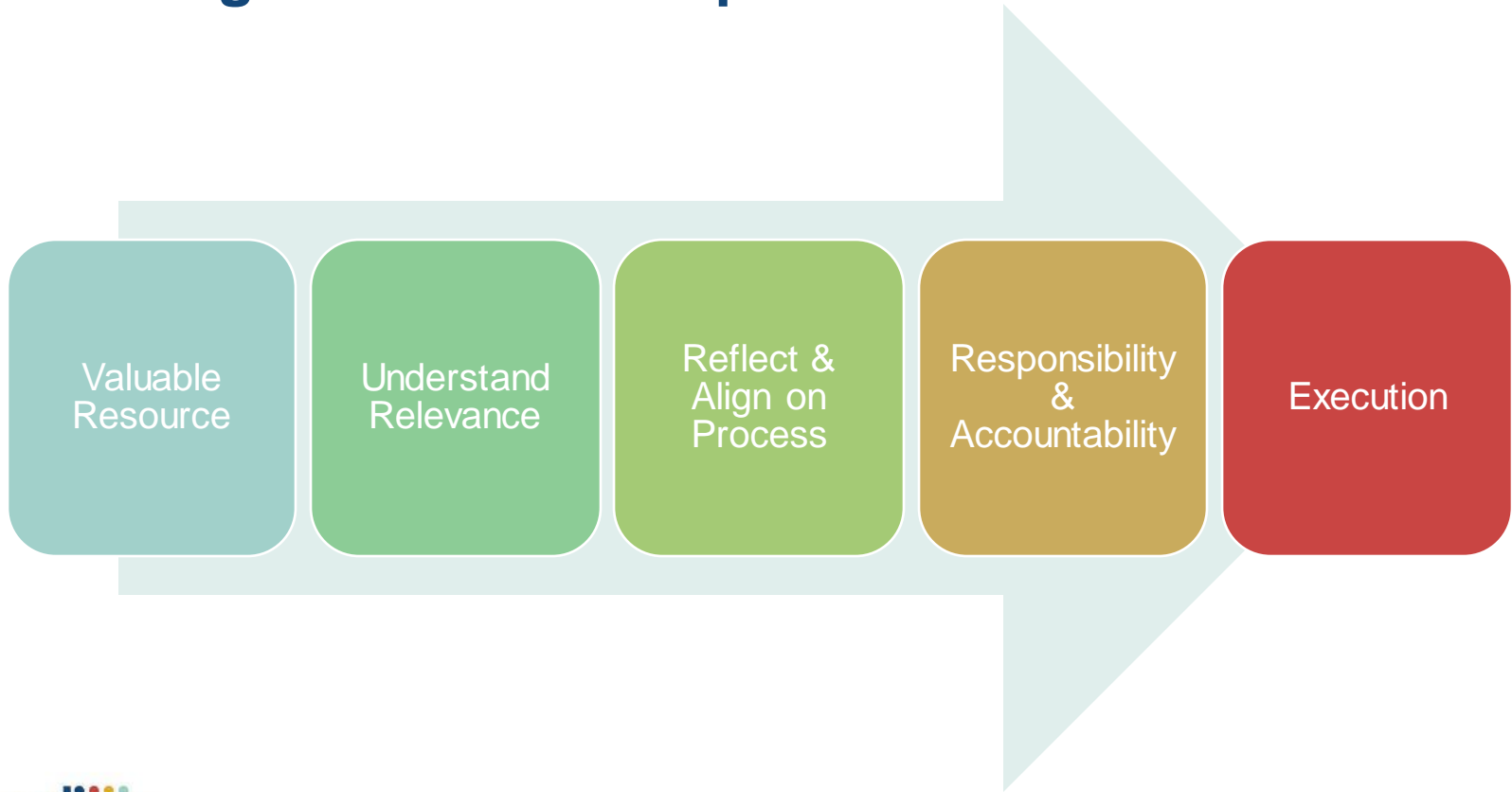
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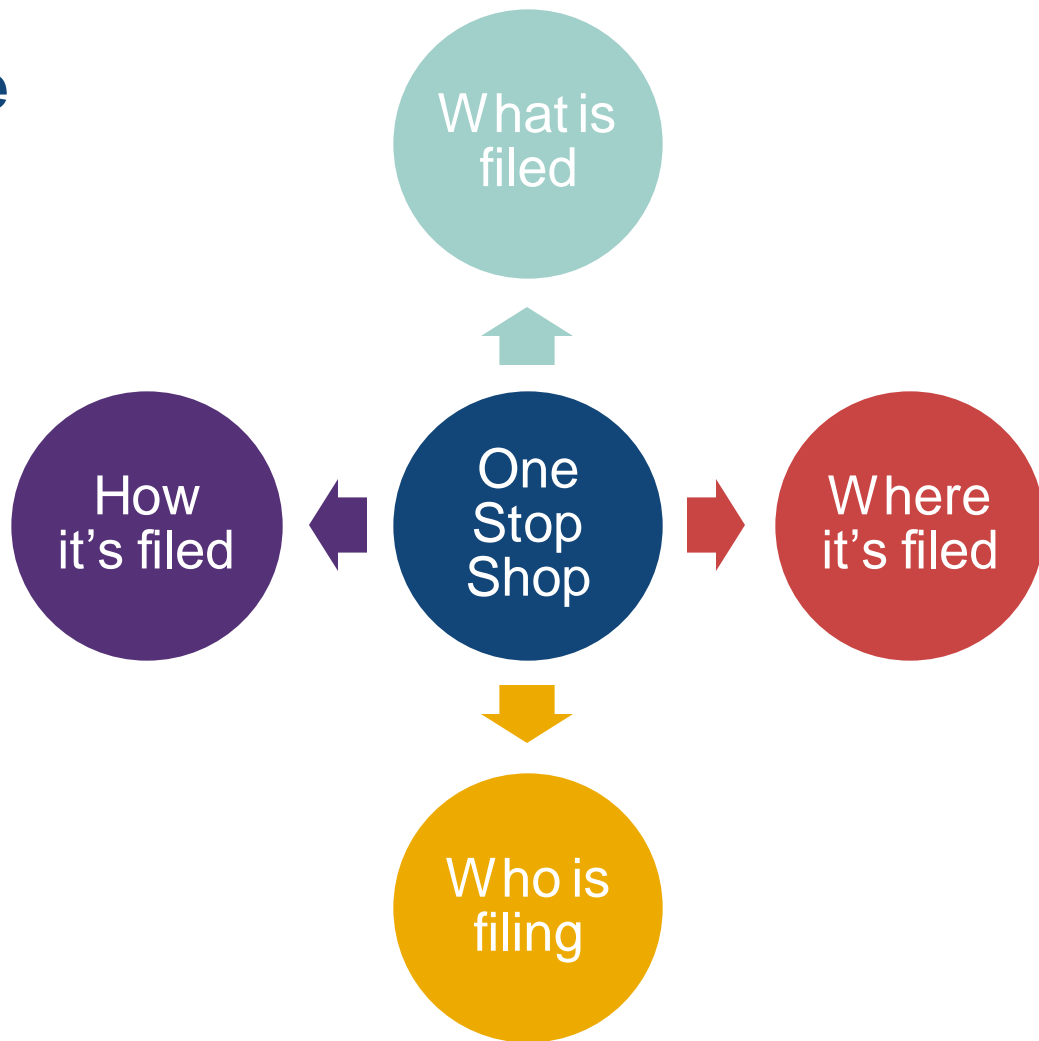
Harnessing the Power of Your TMF Index



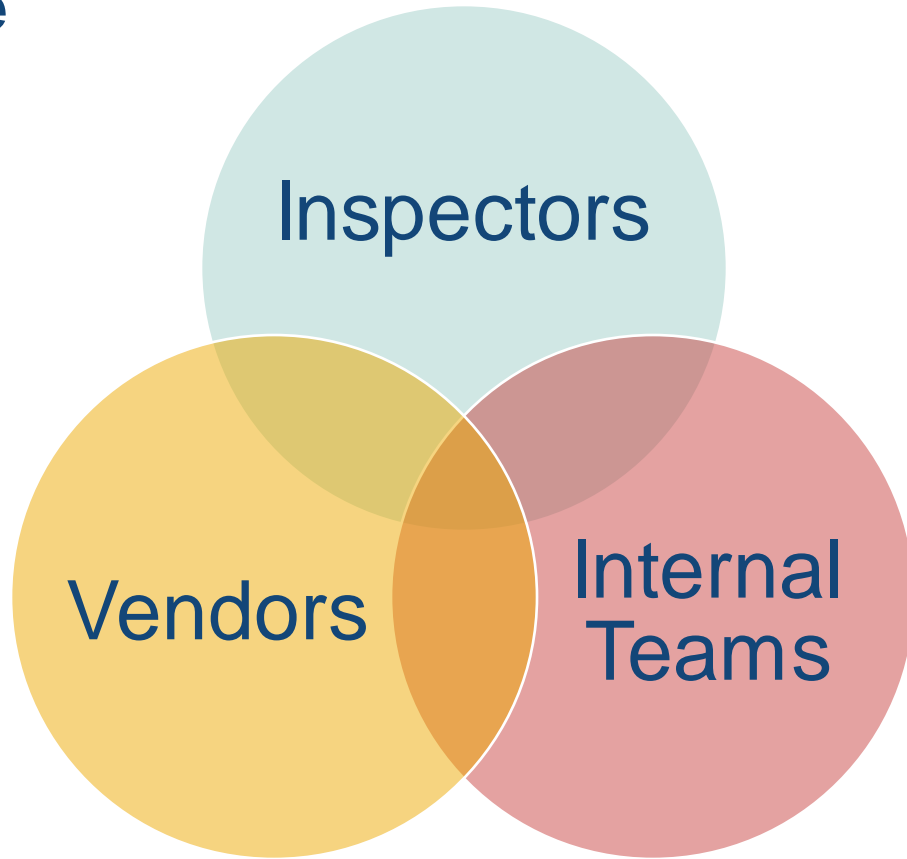
Building Your Index Template



Resource



Relevance



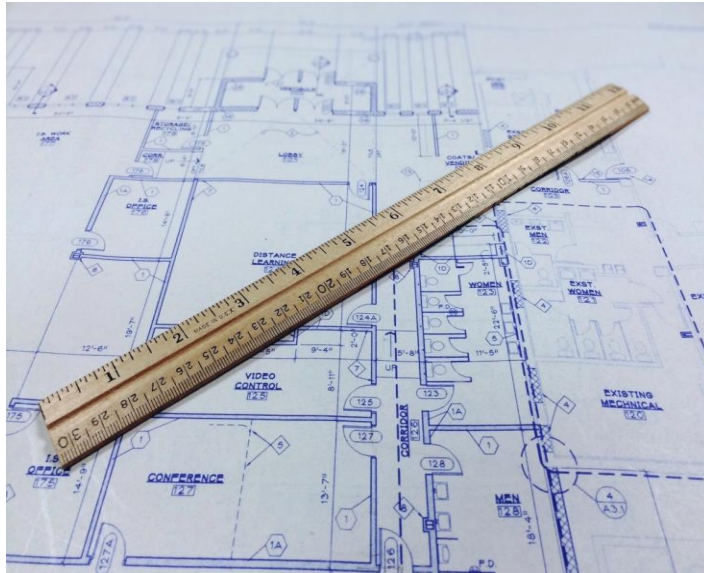
Reflecting Process → Alignment

- Creating standards = understanding how internal teams, vendors and your eTMF function



Responsibility and Accountability

- How can expectations be met without a solidified approach and standards?



TMF Management Execution with Confidence

Let go of
expectations.
Let go of your
attachment to
outcomes.

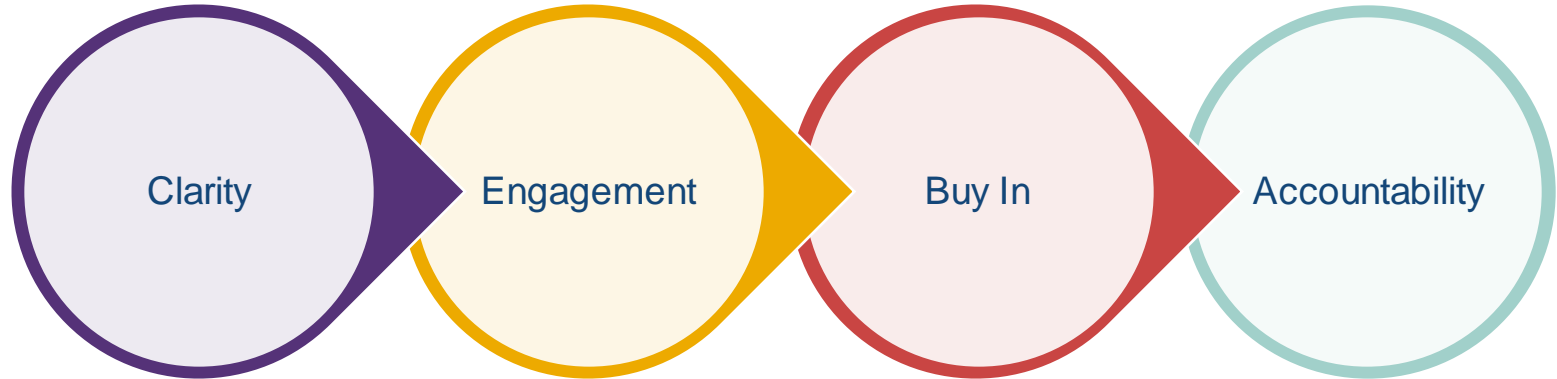
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That feeling you get when self-care
strategy and TMF management
principles don't align...

What's Next?

- Review / update TMF Index with what you think you know
- Identify key stakeholders within each department responsible for TMF content
- Meet individually with departmental SMEs for discussion and confirmation of your assumptions



Potential TMF Index Impacts

Content Owner	Comments	Artifact Applicability	Responsibility for Collection	Artifact Location
<ul style="list-style-type: none">• Confirm, revise, discuss, reconfirm	<ul style="list-style-type: none">• i.e. 'Contained in Project Management Plan'• Nuances based on study type / design<ul style="list-style-type: none">• ROW studies only	<ul style="list-style-type: none">• i.e. Marking artifacts as NA, if not applicable across the board	<ul style="list-style-type: none">• Sponsor• CRO• Other Vendor• Both	<ul style="list-style-type: none">• During Study• EOS

Potential TMF Index Impacts

Document Review Type

- Who performs?
- QC Review
- Inspection Readiness Check
- No Check

Completeness Review Timing

- Initial
- Interim
- EOS

Review Instructions

- 10 % sample of comms
- Confirm all versions present

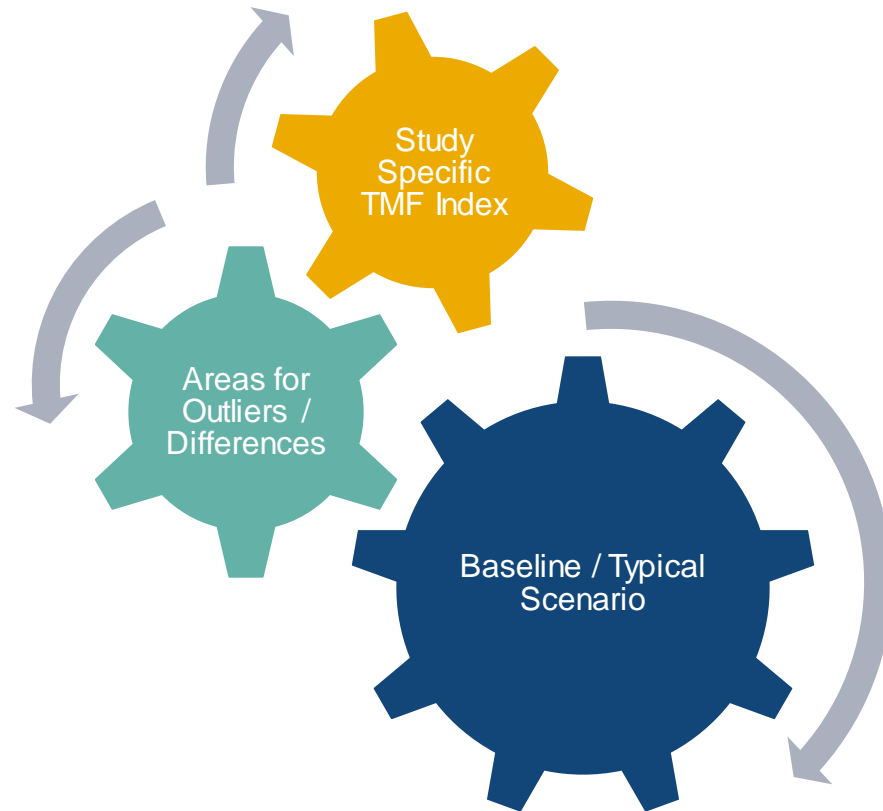
Metadata Review

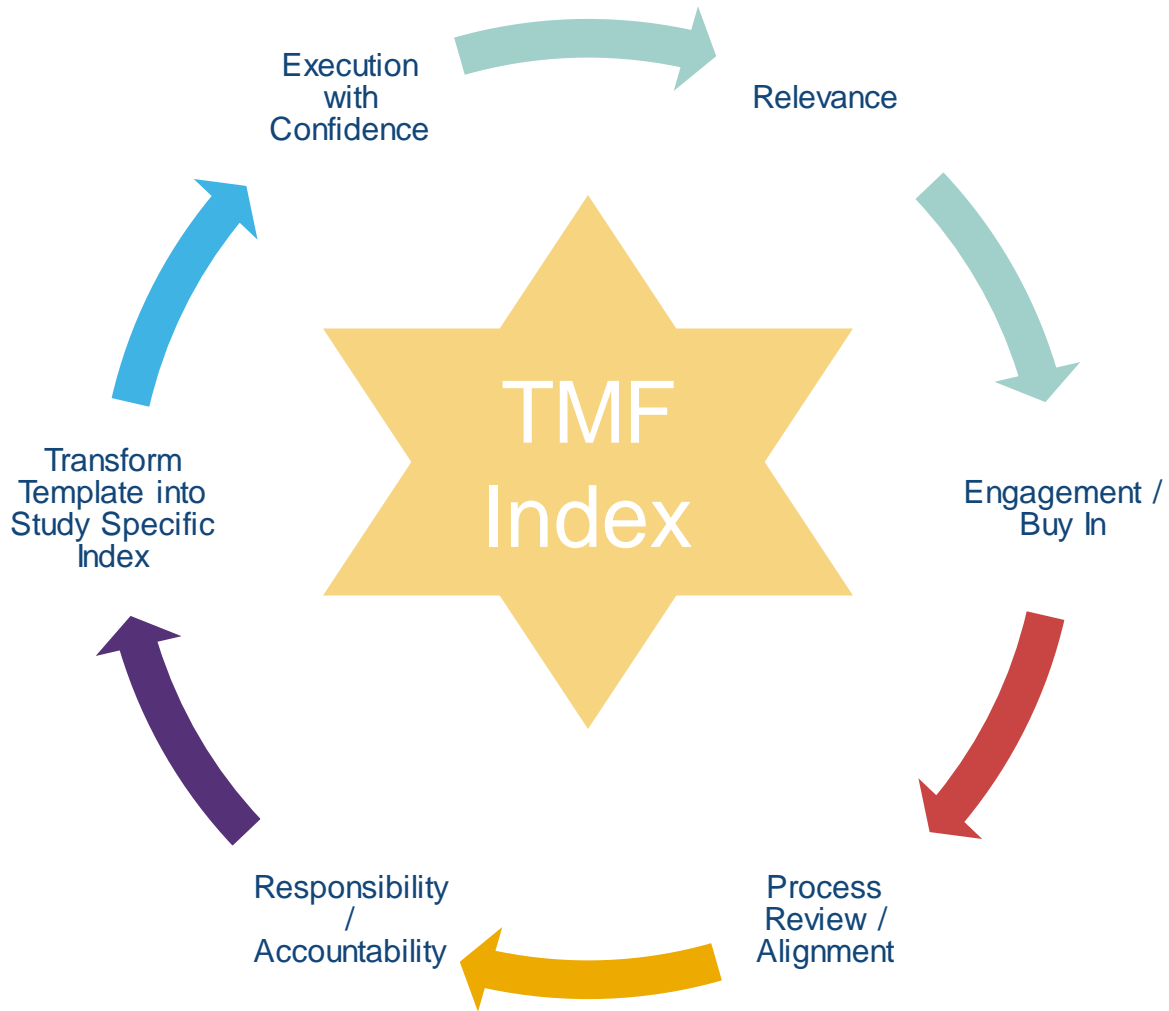
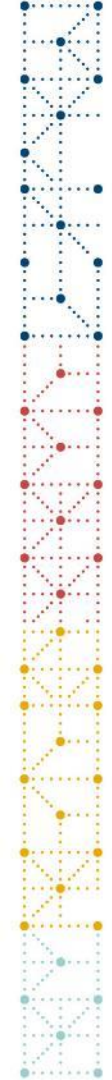
- Dating conventions
- Expiration date
- Language
- Other

Bonus Opportunities



Template Transformation







Thank You!

Laura Wiggins, MBA

Just in Time GCP

Project Manager, Business & Technology Consulting

M. 812.204.1714

lwiggins@justintimegcp.com

[LinkedIn](#) | [JustinTimeGCP®](#)

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