



Building a Multi-Year TMF Strategy

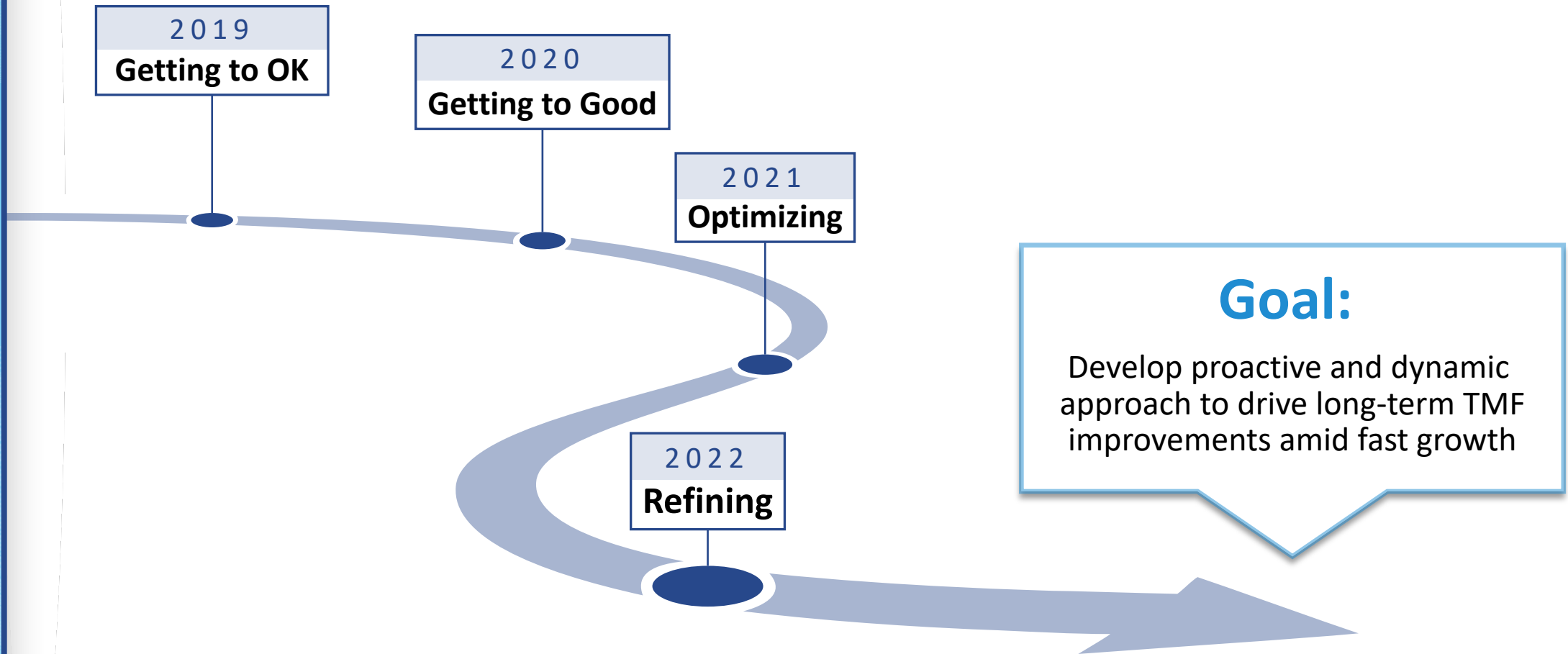


Hi! - I am David Ives

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Goal for Strategy Development



Core components to build a TMF Strategy

- 1** Getting Started
- 2** Defining Vision
- 3** Setting Scope
- 4** Aligning Support and Governance
- 5** Executing
- 6** Monitoring and Adapting



1

Getting Started

Understanding where you have been helps inform where you want to go

Getting Started

*"I don't do TMF. The CRO does that."
- Study team member*



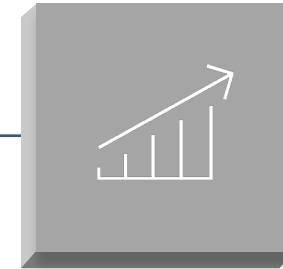
Company/Group Vision

Establish true north by reviewing company and group vision and mission and R&D program



Ongoing Activity

Review ongoing initiatives and list all systems, partnerships, processes, and teams



History of Effort

Learn from previous TMF experience, including audits and inspections, with pattern recognition in inspection findings

2

Defining Vision

A clear vision can be the base for all you do

Alexion's TMF Vision



TMF is a central repository and serves as the single source for all information necessary to reconstruct a clinical trial and prove GCP compliance. All study team members are accountable for regularly maintaining the TMF throughout a study.

A TMF Vision:

- Ambitiously defines the **'what'**
- Gives a **'why'**
- Sets expectations across functions

3

Setting Scope

You may be able to do it all, but you can't do it all at once

Setting Scope

Cohesive Components

Define the core components of your TMF strategy and create a framework to stay on-mission with leadership alignment

Processes



Standards for end-to-end TMF operations

Accountability



Accountability and proactive issue management beyond compliance

Culture



Continuous education on TMF and its important role in drug development

Systems



Infrastructure implementation and support

4

Aligning Support and Governance

You may be able to do it all, but you can't do it all alone

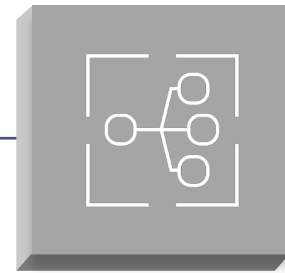
Aligning Support and Governance



**Map out
stakeholders**



**Get leadership support,
including budget and
resources**

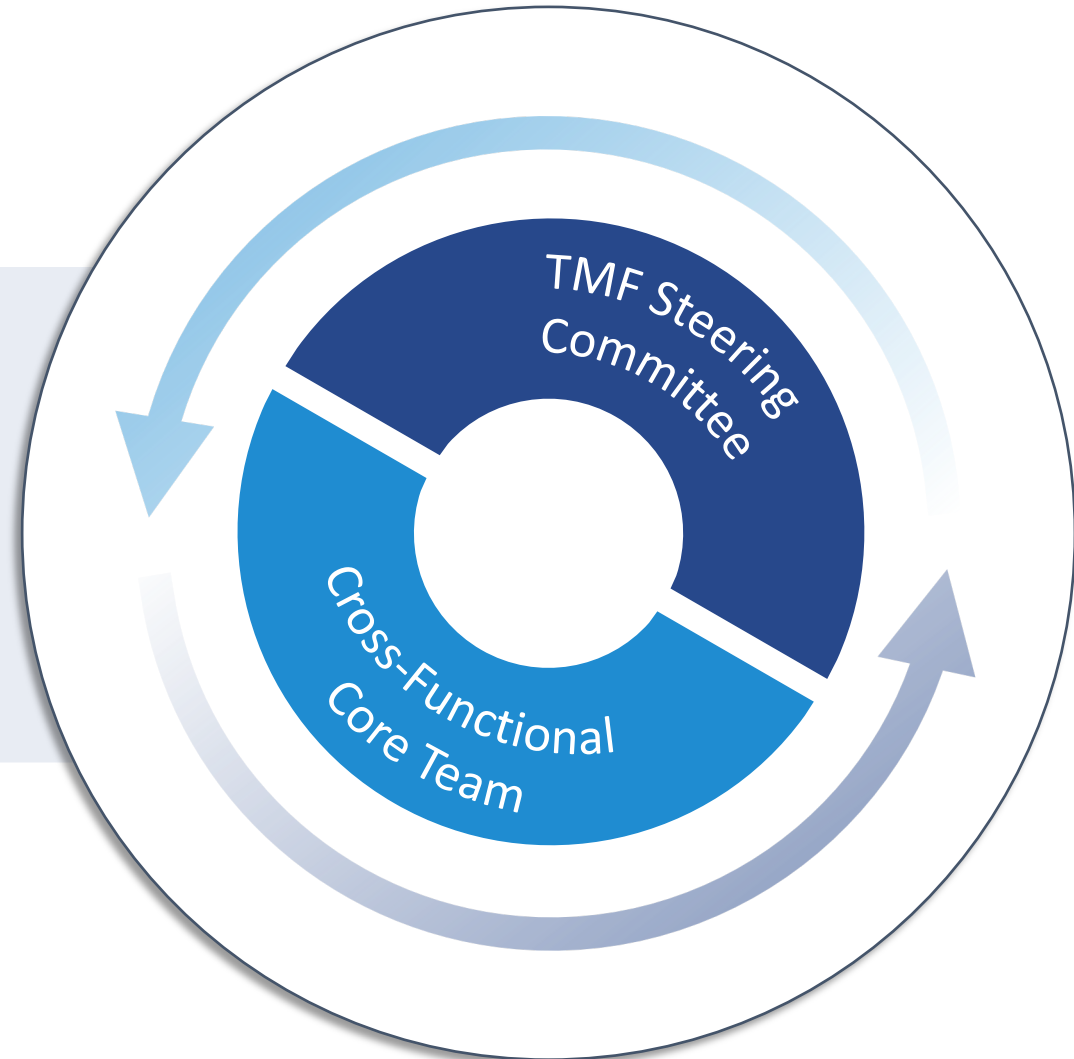


**Deploy a tiered TMF
governance structure**

TMF Governance Structure

Supporting Oversight Resources

- TMF Governance Charter
- TMF Metrics Dashboard



Oversight Resources Defined

TMF Governance Charter

Document to define function and responsibilities of steering committee and cross-functional core team

TMF Metrics Dashboard

Shared dashboard to provide transparency into KPIs and drive inspection readiness core team

TMF Compliance Plan

Think internal audit plan for TMF process, matched to key studies aligned to R&D objectives; revise processes based on results

TMF Program Plan

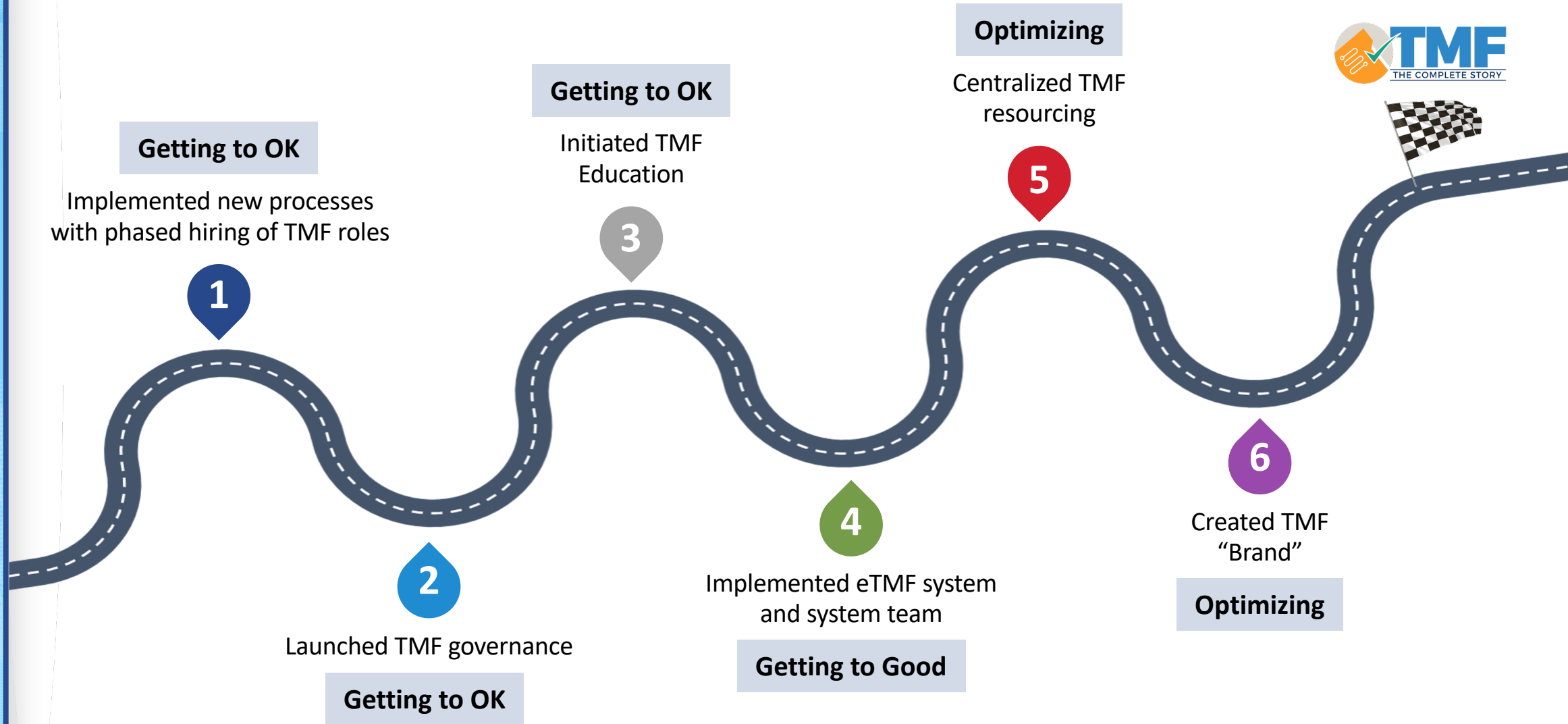
Pre-defined program that removes need for additional approval and sets the tone for the year; adapt on an annual basis to evolve strategy

5

Executing

Knowing where you are going is only the beginning of the fun

Alexion Strategic Journey



Strategic Activities Defined

		<i>Timing</i>
1 New Processes	<i>Define new processes to drive multi-year strategy, including detection methods</i>	<i>5 months from napkin scratch to trained and effective</i>
2 TMF Governance	<i>Split TMF governance between steering committee and cross-functional core team</i>	<i>3 months from target to kick-off</i>
3 eTMF System	<i>Implement eTMF system and team to support successful adoption and change management</i>	<i>18 months from initial pitch to go-live</i>
4 TMF Education Program	<i>Educate study teams on value of TMF and use of eTMF system</i>	<i>2 months for initial approach; 9 months for branding and e-learning</i>
5 Centralized TMF Resourcing	<i>Centralize TMF oversight to reinforce governance model and processes</i>	<i>6 months from design to implementation</i>

6

Monitoring and Adapting

You've done something, so now what?

“

**However beautiful the strategy, you
should occasionally look at the results.**

Sir Winston Churchill

”

Monitoring and Adapting TMF Strategy

1

Monitoring Your TMF Strategy

Establish mechanisms for monitoring your strategy beyond audits. We created a mechanism for evaluating processes each year through the lens of key studies

2

Adapting Your TMF Strategy

Set up pre-planned approaches to adapt your strategy so you have agreed upon pathways for change when needed

Supporting Oversight Resources

- 🕒 TMF Compliance Plan
- 🕒 TMF Program Plan

Oversight Resources Defined

TMF Governance Charter	<i>Document to define function and responsibilities of steering committee and cross-functional core team</i>
TMF Metrics Dashboard	<i>Shared dashboard to provide transparency into KPIs and drive inspection readiness core team</i>
TMF Compliance Plan	<i>Think internal audit plan for TMF process, matched to key studies aligned to R&D objectives; revise processes based on results</i>
TMF Program Plan	<i>Pre-defined program that removes need for additional approval and sets the tone for the year; adapt on an annual basis to evolve strategy</i>

Next Steps



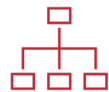
Continue to drive inspection readiness



Develop TMF storyboards for every study



**Grow and manage new programs
in pipeline**



Maintain governance structure



Support ongoing education

Final Takeaway



**Think Vision
Not Tactics**

Thanks!
Any questions?

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