

2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



From Transactional Support to Trusted Partnership: Achieving TMF Excellence Together

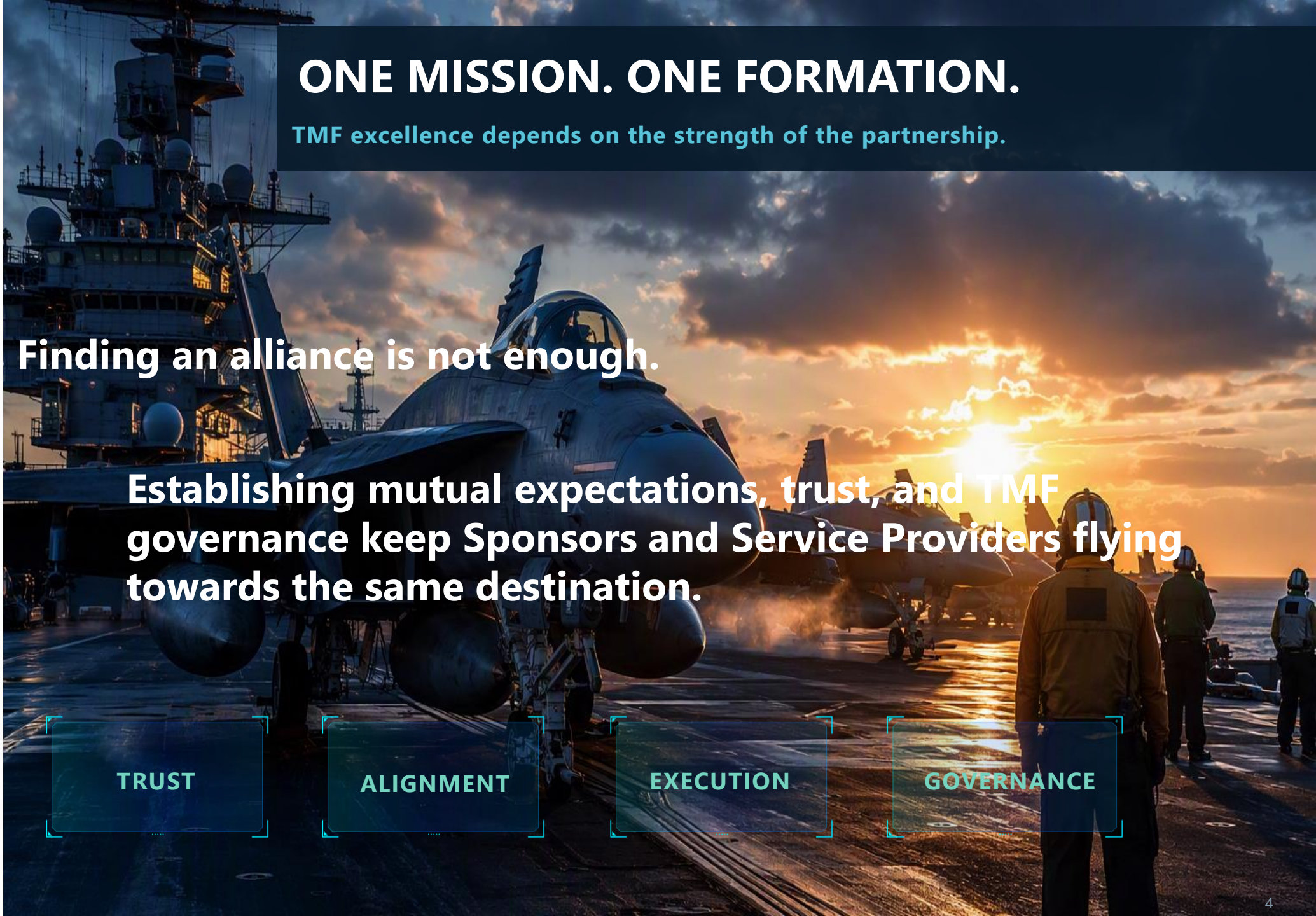
Disclaimer and Disclosures

- The views and opinions expressed in this presentation are those of the Seth and Jared and do not necessarily reflect the official policy or position of their employer, nor CDISC.


MISSION BRIEF
MISSION:
TMF EXCELLENCE
From transactional support to trusted partnership
MAVERICK
ICEMAN
PHOENIX
JARED BROOSLIN
Senior Manager, Trial Master File
Intellia Therapeutics
FLIGHT CREW
Two perspectives. One mission.
SETH PEARL
Head of Commercial
Phlexglobal

ONE MISSION. ONE FORMATION.

TMF excellence depends on the strength of the partnership.



Finding an alliance is not enough.

Establishing mutual expectations, trust, and TMF governance keep Sponsors and Service Providers flying towards the same destination.

- TRUST
- ALIGNMENT
- EXECUTION
- GOVERNANCE

MISSION FLIGHT PLAN

From selecting the right partner to sustaining strategic impact.

01	**SELECT THE WING PARTNER**	Capabilities • Commercial model & value • Future fit	LAUNCH
02	**BUILD THE FLIGHT PLAN**	Clear Roles and Expectations • Operating model	FORM
03	**ALIGN BEFORE TAKE-OFF**	Mutual Objectives • Scope	ALIGN
04	**NAVIGATE TURBULANCE**	Execution • Communication • TMF confidence	EXECUTE
05	**DEBRIEF**	Risk management • Continuous improvement • Shared success	ACCELERATE

ALIGN EARLY • EXECUTE TOGETHER • SCALE SUCCESS

SELECTING YOUR WING PARTNER

From first transaction to a long-term strategic relationship.



CAPABILITY FIT

Can they deliver with confidence?

- ✓ Proven TMF operating expertise
- ✓ Partner can lead with TMF best practices
- ✓ Technology and AI-forward roadmap

COMMERCIAL FIT

Is the operating model delivering value?

- ✓ Value aligned to the investment
- ✓ Flexibility as volumes change
- ✓ Clear scope and accountability

FUTURE FIT

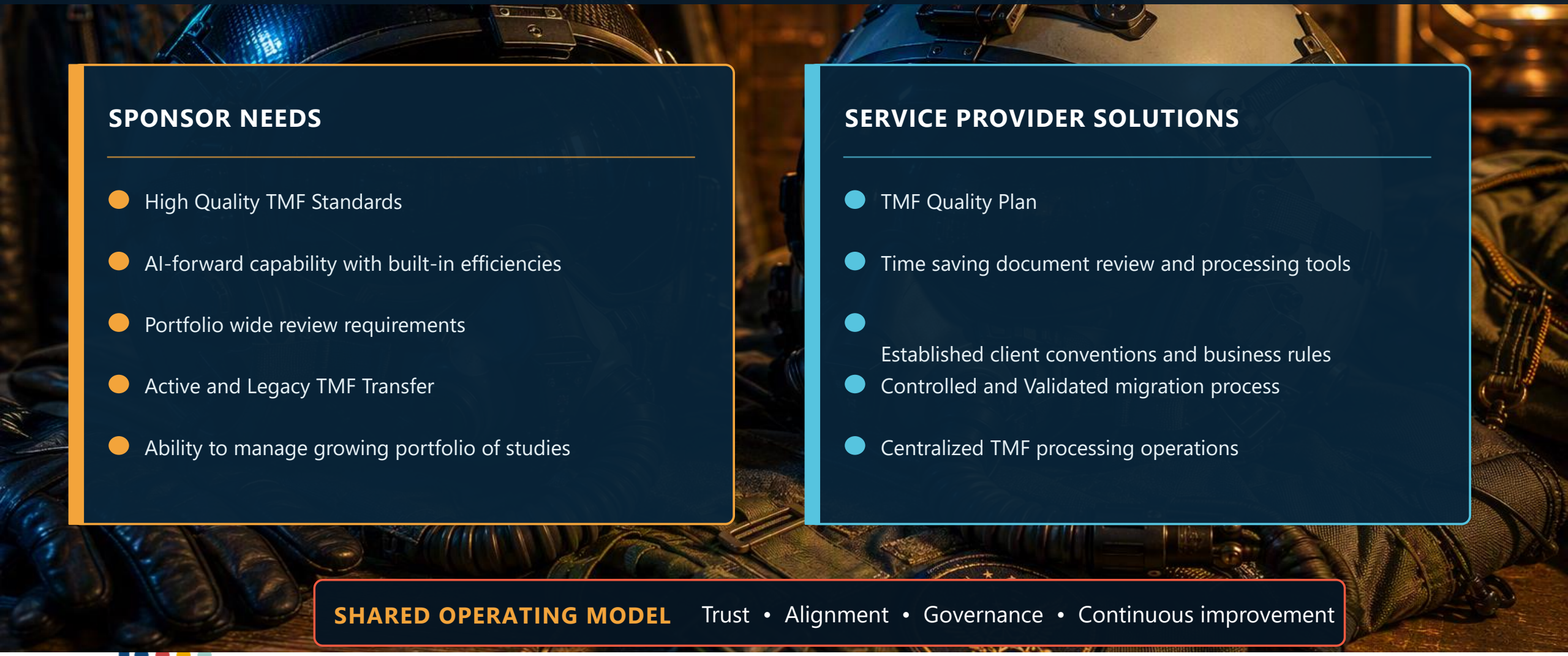
Can the partnership evolve?

- ✓ Scales with the portfolio
- ✓ Adapts priorities as industry standards and regulations change
- ✓ Commitment beyond the transaction

MISSION-CRITICAL TEST **Strategic alignment must be explicit from day one.**

BUILD THE FLIGHT PLAN

What each partner needs to bring to the TMF operating model.



SPONSOR NEEDS

- High Quality TMF Standards
- AI-forward capability with built-in efficiencies
- Portfolio wide review requirements
- Active and Legacy TMF Transfer
- Ability to manage growing portfolio of studies

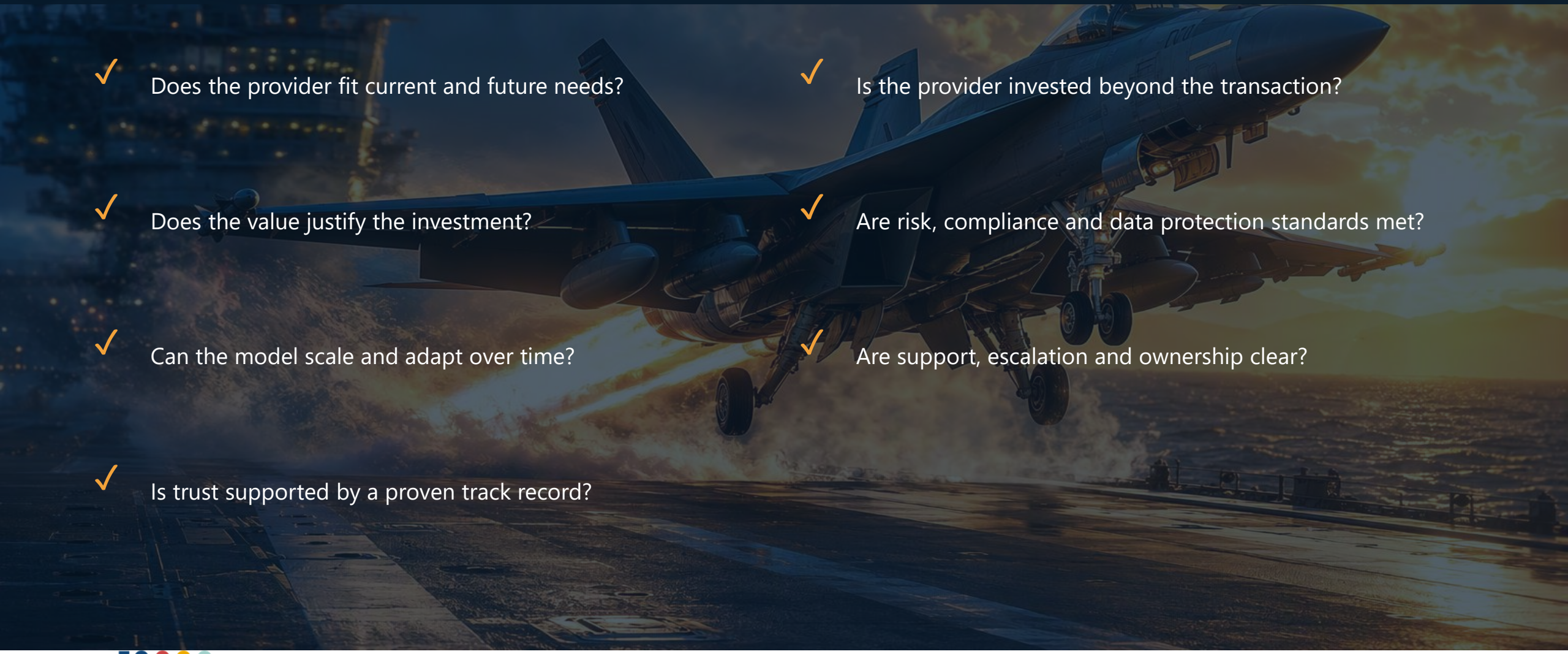
SERVICE PROVIDER SOLUTIONS

- TMF Quality Plan
- Time saving document review and processing tools
- Established client conventions and business rules
- Controlled and Validated migration process
- Centralized TMF processing operations

SHARED OPERATING MODEL Trust • Alignment • Governance • Continuous improvement

PRE-FLIGHT CHECKLIST - Reflection

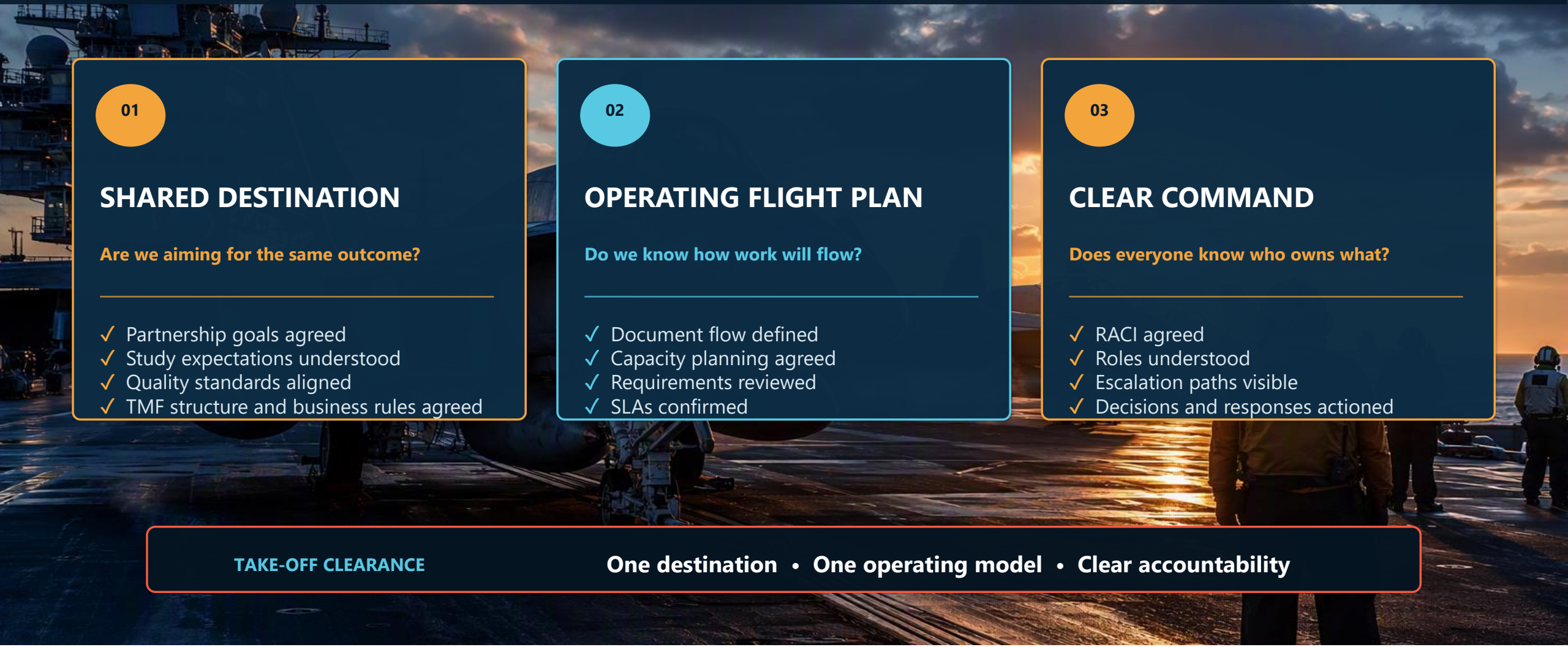
Questions to ask before selecting a service provider.



- ✓ Does the provider fit current and future needs?
- ✓ Is the provider invested beyond the transaction?
- ✓ Does the value justify the investment?
- ✓ Are risk, compliance and data protection standards met?
- ✓ Can the model scale and adapt over time?
- ✓ Are support, escalation and ownership clear?
- ✓ Is trust supported by a proven track record?

ALIGN BEFORE TAKE-OFF

Are both organizations flying towards the same destination?



01

SHARED DESTINATION

Are we aiming for the same outcome?

- ✓ Partnership goals agreed
- ✓ Study expectations understood
- ✓ Quality standards aligned
- ✓ TMF structure and business rules agreed

02

OPERATING FLIGHT PLAN

Do we know how work will flow?

- ✓ Document flow defined
- ✓ Capacity planning agreed
- ✓ Requirements reviewed
- ✓ SLAs confirmed

03

CLEAR COMMAND

Does everyone know who owns what?

- ✓ RACI agreed
- ✓ Roles understood
- ✓ Escalation paths visible
- ✓ Decisions and responses actioned

TAKE-OFF CLEARANCE — **One destination • One operating model • Clear accountability**

CRUISING ALTITUDE

Joint vision and TMF governance translate into operational confidence.

SPONSOR OUTCOMES

- ✓ Quality and Inspection ready TMF confidence
- ✓ Operational transparency and understanding
- ✓ Scalable document management
- ✓ TMF Governance and trust

SERVICE PROVIDER CONTRIBUTION

- ✓ Expertise and guidance
- ✓ Opportunity to stop and reflect
- ✓ Continuous improvement
- ✓ Quality and compliance leadership

01 **CONFIDENCE**

02 **TRANSPARENCY**

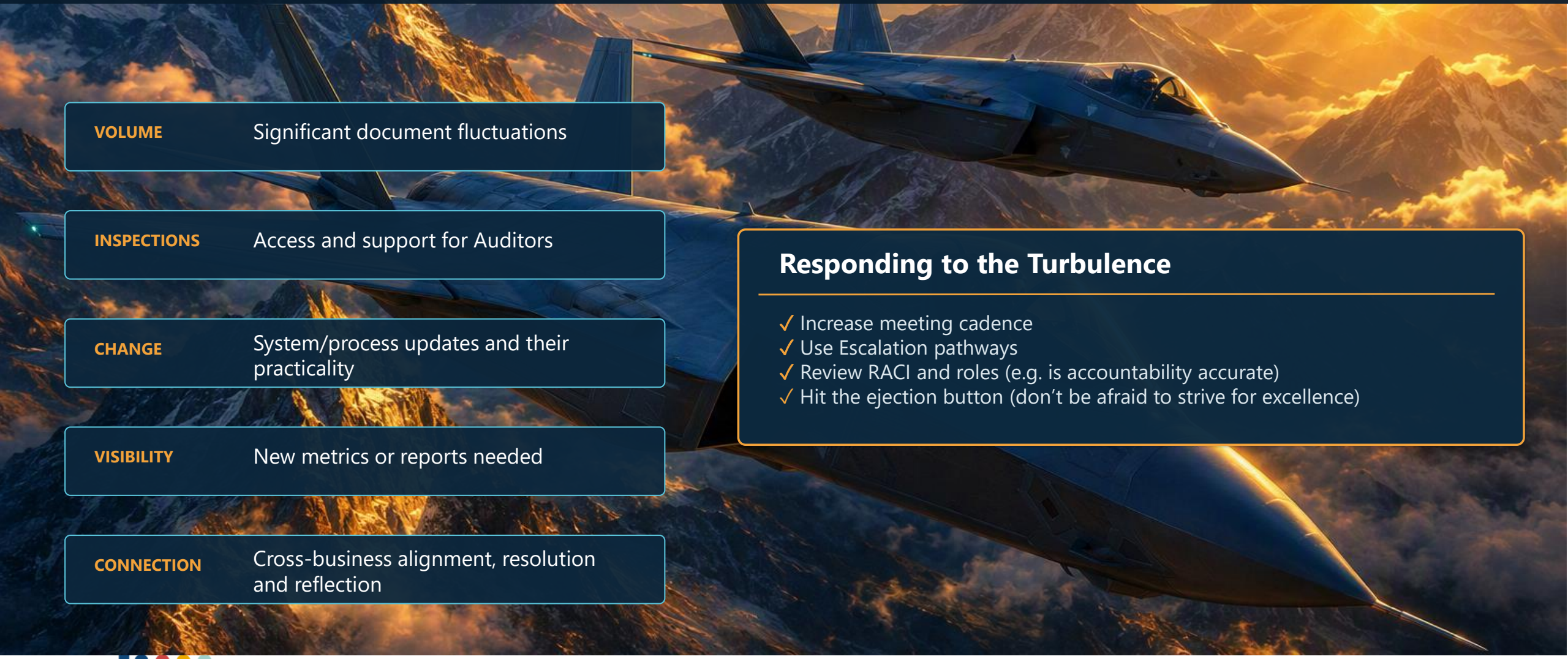
03 **EXPERTISE**

04 **IMPROVEMENT**

05 **LEADERSHIP**

NAVIGATING TURBULENCE

Course correcting when things are bumpy



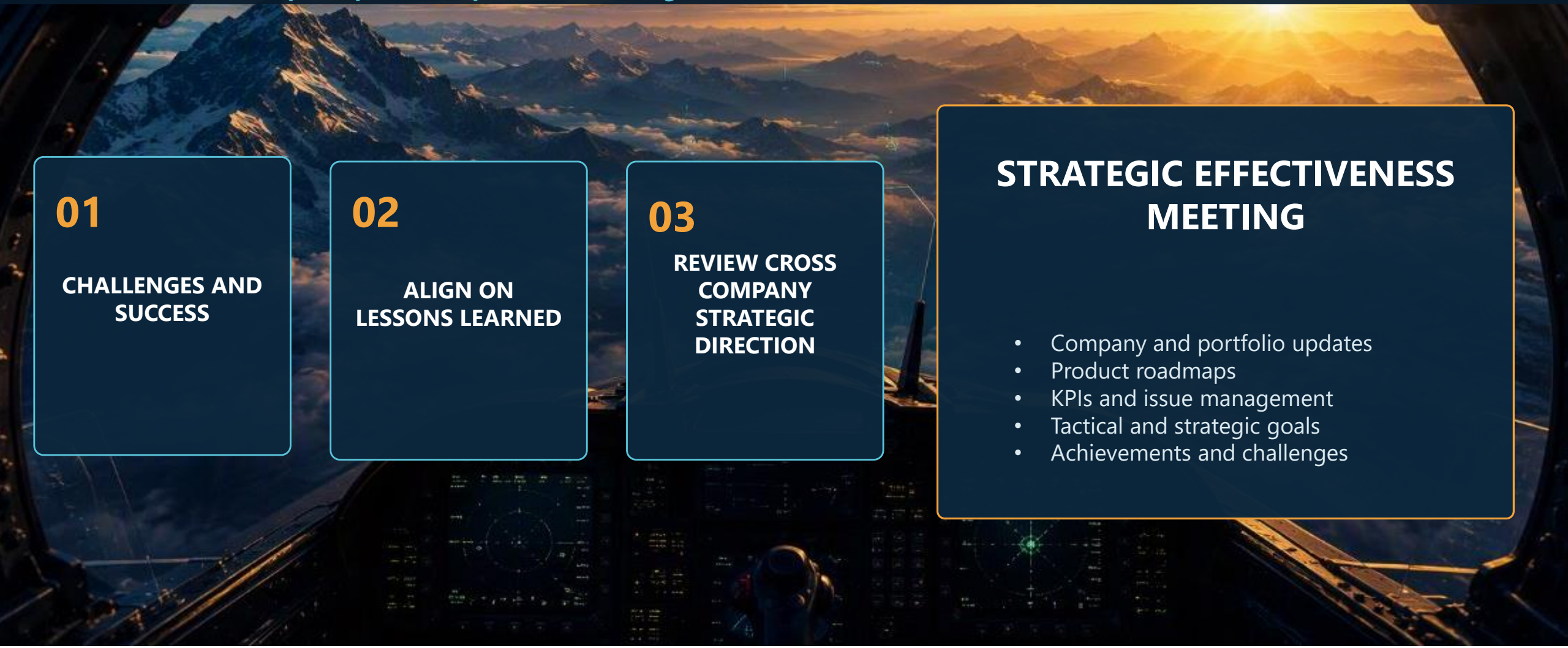
VOLUME	Significant document fluctuations
INSPECTIONS	Access and support for Auditors
CHANGE	System/process updates and their practicality
VISIBILITY	New metrics or reports needed
CONNECTION	Cross-business alignment, resolution and reflection

Responding to the Turbulence

- ✓ Increase meeting cadence
- ✓ Use Escalation pathways
- ✓ Review RACI and roles (e.g. is accountability accurate)
- ✓ Hit the ejection button (don't be afraid to strive for excellence)

DEBRIEF

Three controls keep the partnership on course and governance in check.



01

CHALLENGES AND SUCCESS

02

ALIGN ON LESSONS LEARNED

03

REVIEW CROSS COMPANY STRATEGIC DIRECTION

STRATEGIC EFFECTIVENESS MEETING

- Company and portfolio updates
- Product roadmaps
- KPIs and issue management
- Tactical and strategic goals
- Achievements and challenges

MISSION ACCOMPLISHED

The capabilities that turn a service relationship into a strategic partnership.



FLY FURTHER. TOGETHER.

Clear alignment. Strong governance. Reliable execution.
Shared success.

- INSPECTION CONFIDENCE
- TMF ACCESS AND OVERISGHT
- MUTAL RESPECT & TRANSPARENCY
- CONFIDENCE IN SCALABILITY

Thank You!



Questions?

