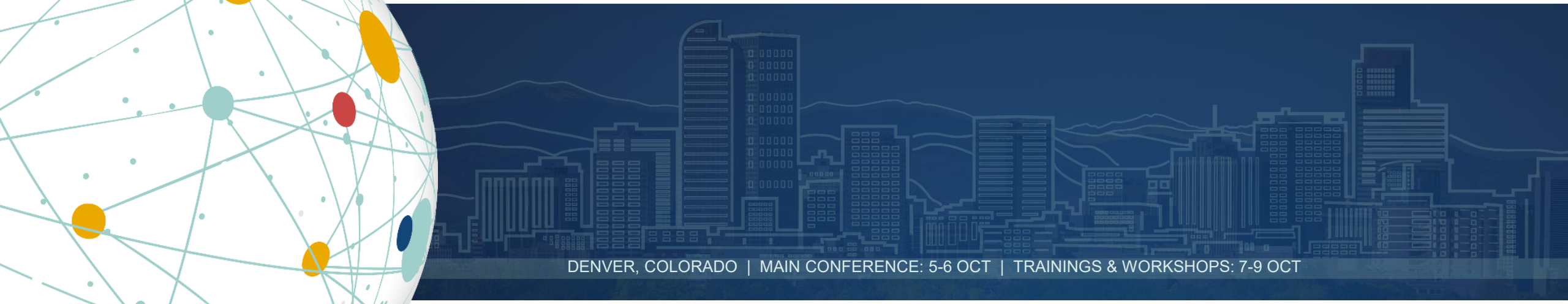


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2026 US Interchange

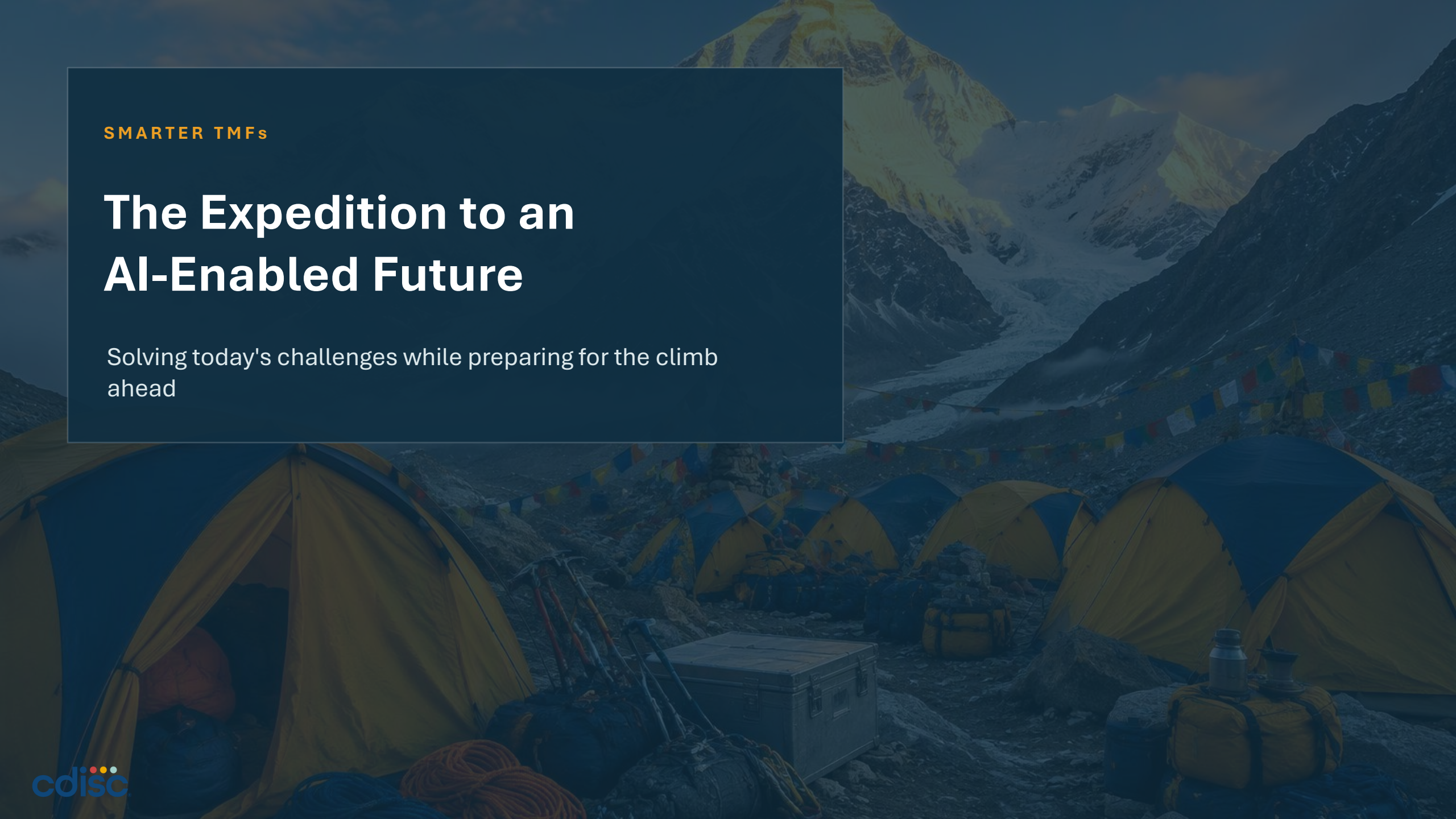
THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Smarter TMFs: Solving Today's Challenges While Preparing for an AI-Enabled Future

Christina Allen, Associate Director, Daiichi Sankyo, Inc.
Angie Gill, Lead Customer Success Manager, Phlexglobal, Inc.

The views and opinions expressed in the following PowerPoint slides are those of the individual presenters and should not be attributed to Phlexglobal, Inc., Daiichi Sankyo, Inc., its directors, officers, employees, or affiliates, or any organization with which the presenters are employed or affiliated.



SMARTER TMFs

The Expedition to an AI-Enabled Future

Solving today's challenges while preparing for the climb ahead

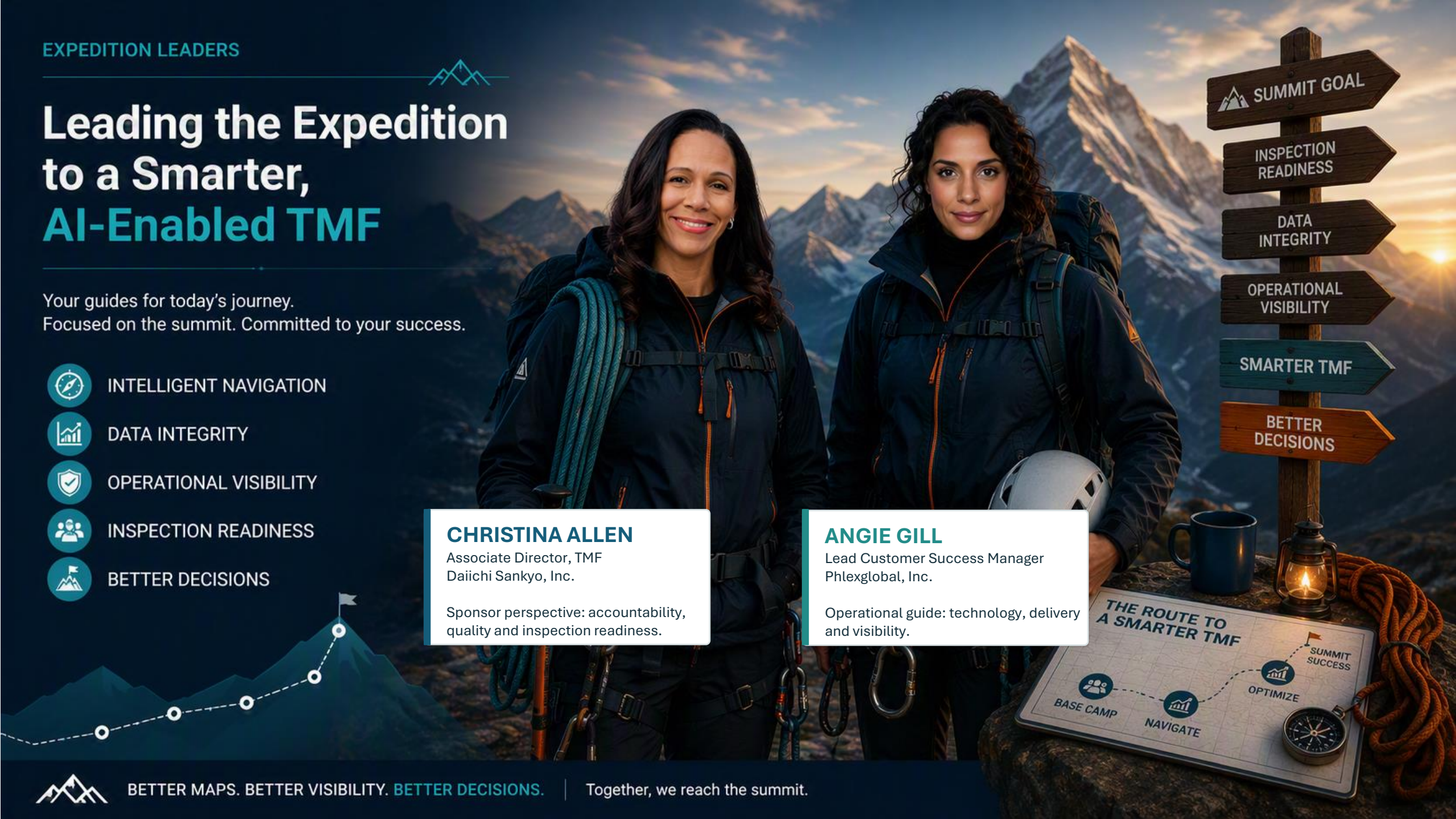
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EXPEDITION LEADERS

Leading the Expedition to a Smarter, AI-Enabled TMF

Your guides for today's journey.
Focused on the summit. Committed to your success.

- INTELLIGENT NAVIGATION
- DATA INTEGRITY
- OPERATIONAL VISIBILITY
- INSPECTION READINESS
- BETTER DECISIONS



CHRISTINA ALLEN
Associate Director, TMF
Daiichi Sankyo, Inc.

Sponsor perspective: accountability, quality and inspection readiness.

ANGIE GILL
Lead Customer Success Manager
Phlexglobal, Inc.

Operational guide: technology, delivery and visibility.

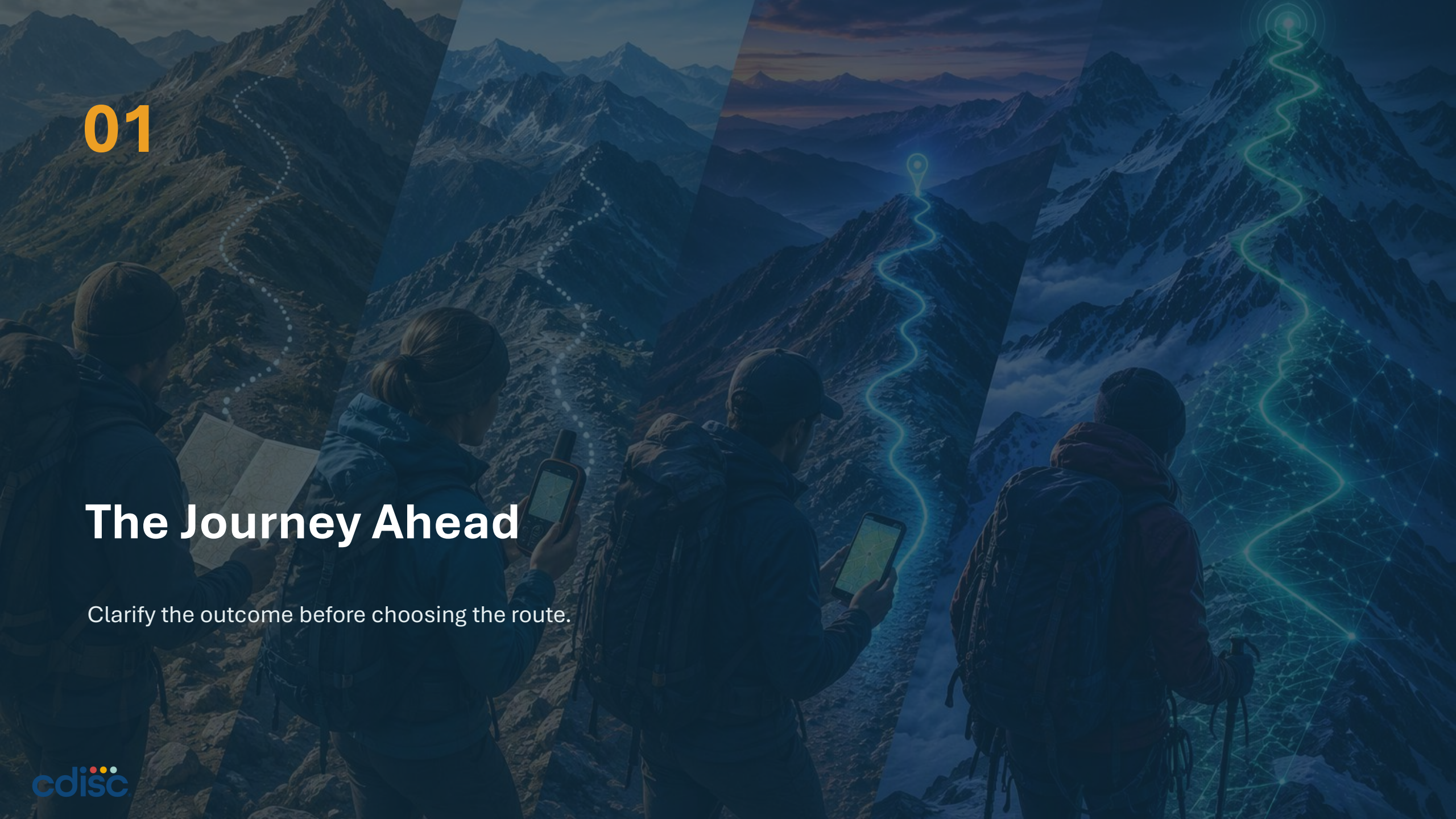
BETTER MAPS. BETTER VISIBILITY. BETTER DECISIONS. | Together, we reach the summit.

EXPEDITION MAP

The Route to the Summit



AI helps illuminate the route. People still lead the climb.



01

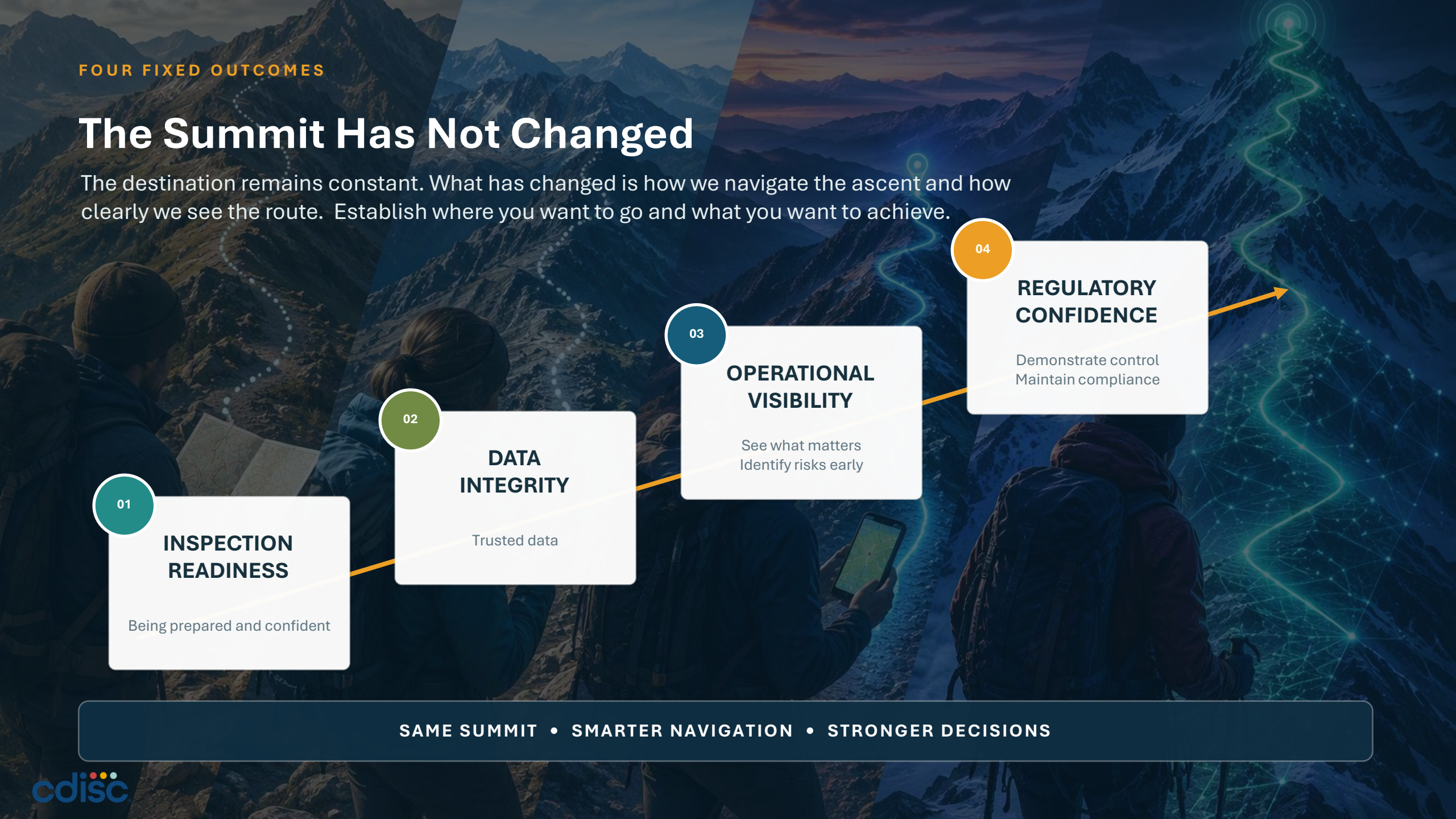
The Journey Ahead

Clarify the outcome before choosing the route.

FOUR FIXED OUTCOMES

The Summit Has Not Changed

The destination remains constant. What has changed is how we navigate the ascent and how clearly we see the route. Establish where you want to go and what you want to achieve.



01

INSPECTION READINESS

Being prepared and confident

02

DATA INTEGRITY

Trusted data

03

OPERATIONAL VISIBILITY

See what matters
Identify risks early

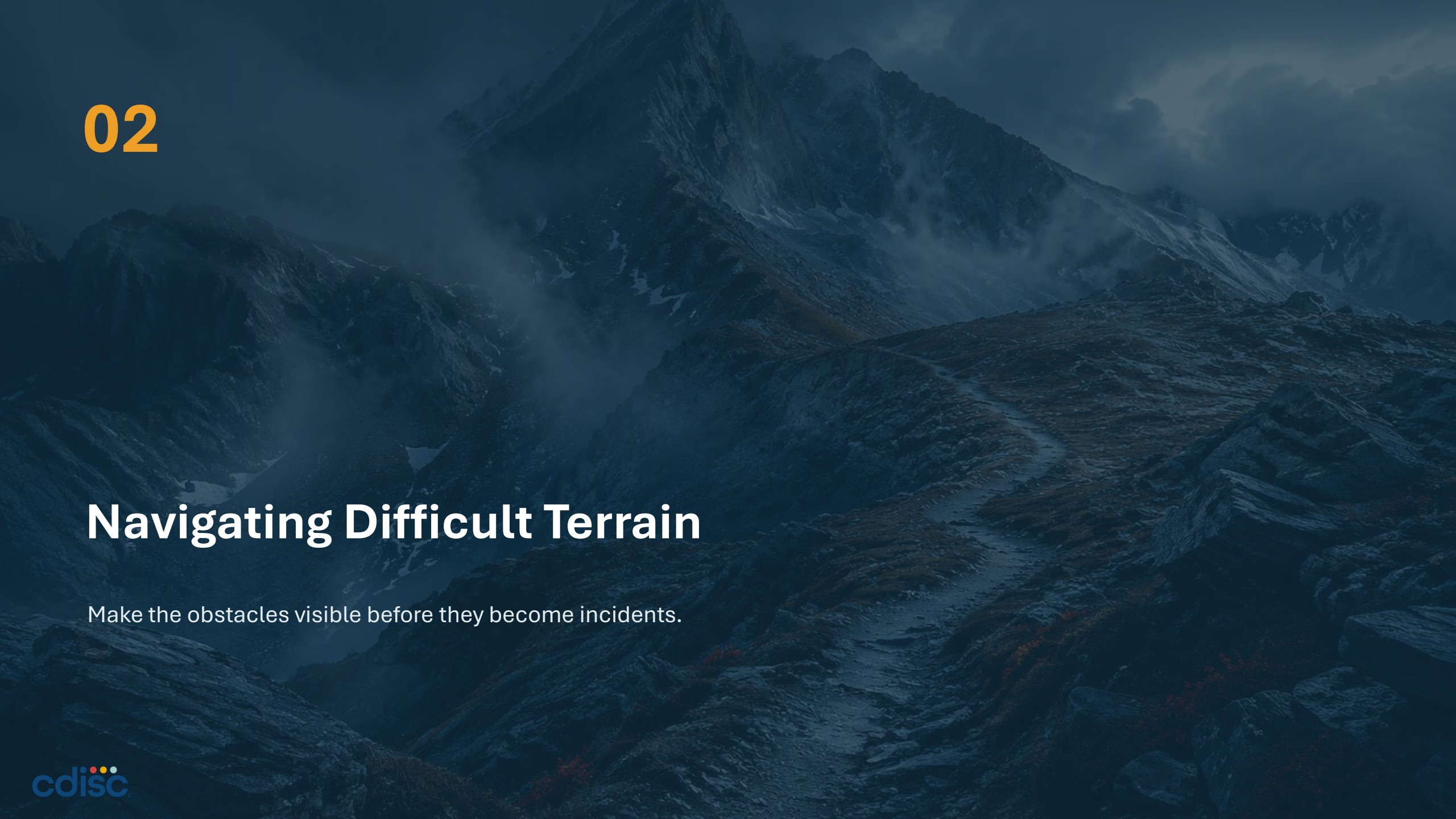
04

REGULATORY CONFIDENCE

Demonstrate control
Maintain compliance

SAME SUMMIT • SMARTER NAVIGATION • STRONGER DECISIONS

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02

Navigating Difficult Terrain

Make the obstacles visible before they become incidents.

FIVE RECURRING OBSTACLES

Read the Terrain Before You Climb

Five common obstacles can turn manageable terrain into inspection pressure.



01 UNCLEAR OWNERSHIP

Who decides?

02 FILING DELAYS

Late movement

03 METADATA VARIABILITY

Unreliable markers

04 QUALITY ISSUES

Hidden hazards

05 LIMITED VISIBILITY

Blind corners

LATE DISCOVERY → REWORK → INCREASED RISK → INSPECTION PRESSURE



03

Establishing Base Camp

AI depends on a strong TMF foundation.

FOUNDATION BEFORE ACCELERATION

Build Base Camp Before the Ascent

AI can strengthen the climb only when four essentials are firmly in place.

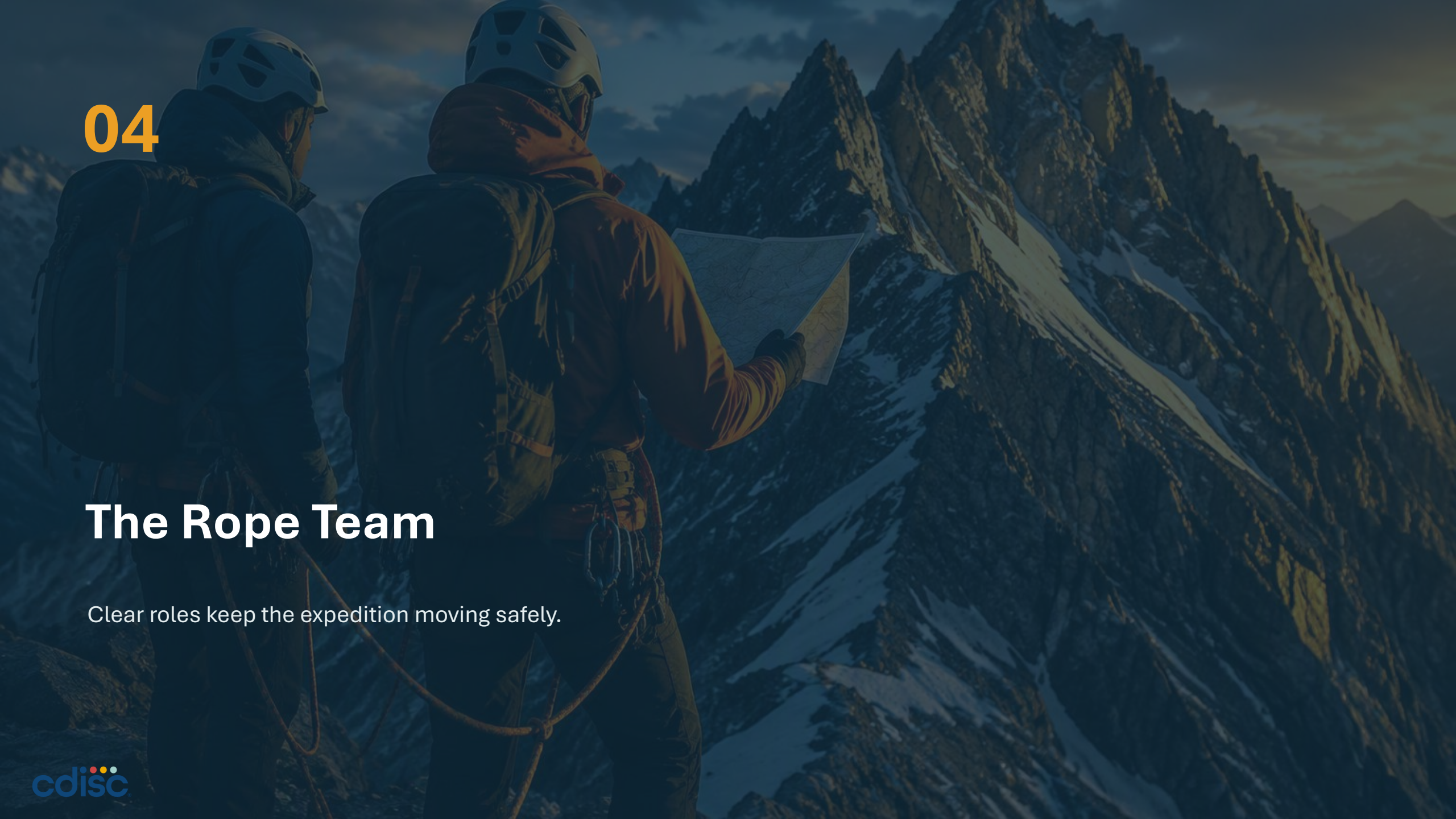
01	**STANDARDS**	CDISC TMF Standard/ taxonomy
02	**GOVERNANCE**	Roles, accountability and oversight
03	**DATA**	Reliable, traceable records
04	**QUALITY**	Metrics, QC and risk monitoring



AI does not fix a weak TMF foundation. It depends on one.

TMF Set-up & Inspection Readiness Playbook, Umbrex, 2025

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04

The Rope Team

Clear roles keep the expedition moving safely.



Who Owns the Route

Before we can optimize the journey, we need to understand who is responsible for guiding the route and ensuring we stay on course.

Clear roles keep the expedition moving safely.

SPONSOR AND VENDOR PARTNERSHIP

One Summit. Distinct Responsibilities.

SPONSOR LEADS

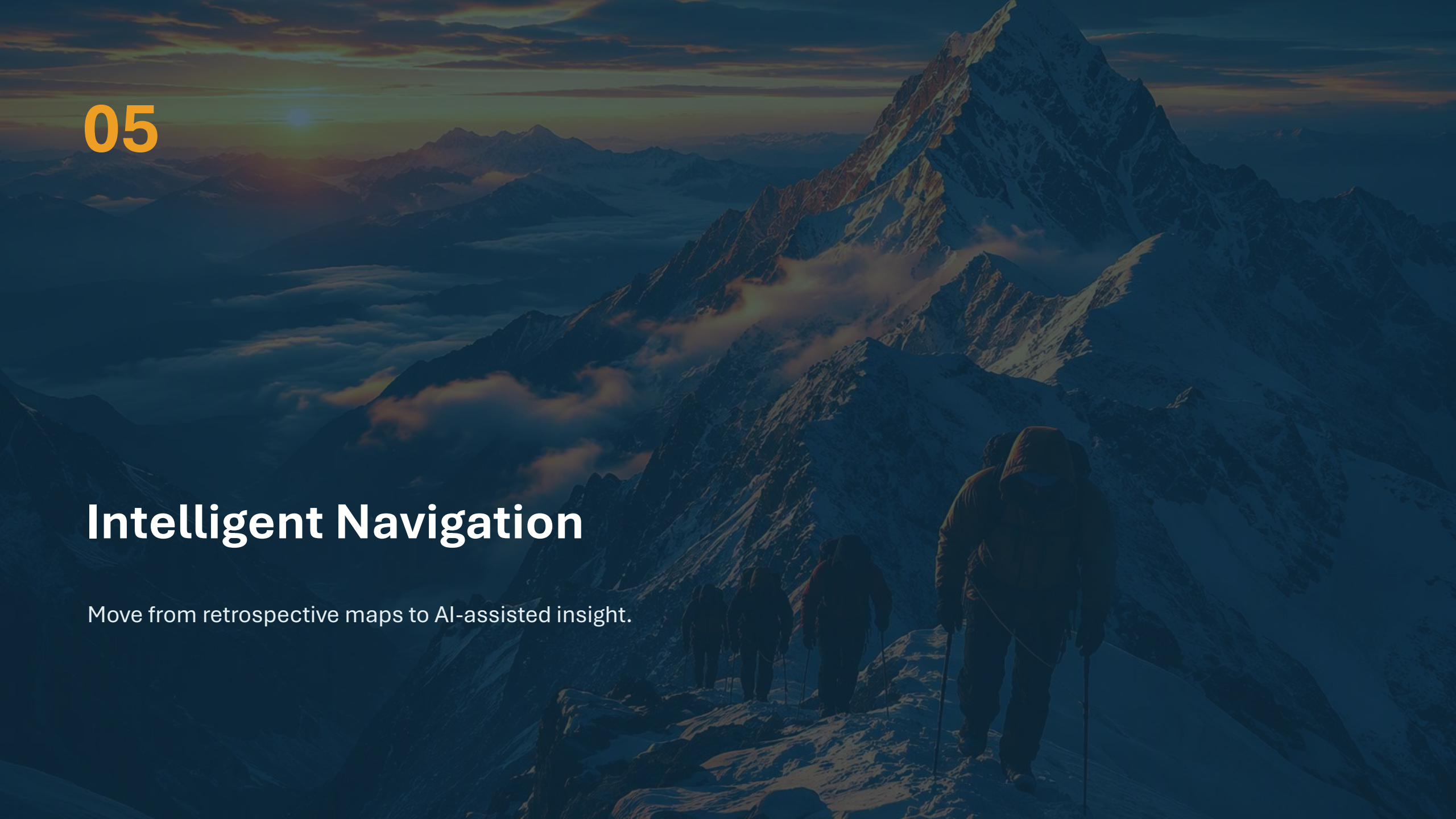
- Regulatory accountability
- Quality expectations
- Risk decisions
- Inspection readiness
- Strategic direction
- Cross-functional oversight

VENDOR GUIDES

- Operational execution
- Quality controls
- Risk monitoring
- Inspection support
- Technology and expertise
- Scalable processes and visibility

A successful journey requires clear ownership and a strong partnership.
Accountability stays with people. AI is navigation, not expedition leadership.

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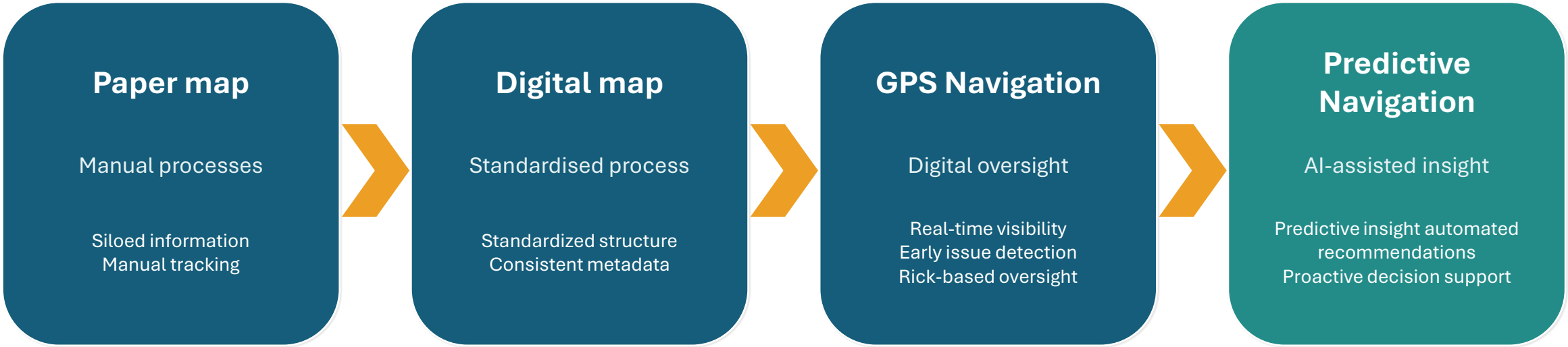
05

Intelligent Navigation

Move from retrospective maps to AI-assisted insight.

What Every Expedition Needs

Evolving our TMF approach-moving from manual processes to AI-assisted insight for better decisions



The destination is constant. The view of the terrain becomes clearer.

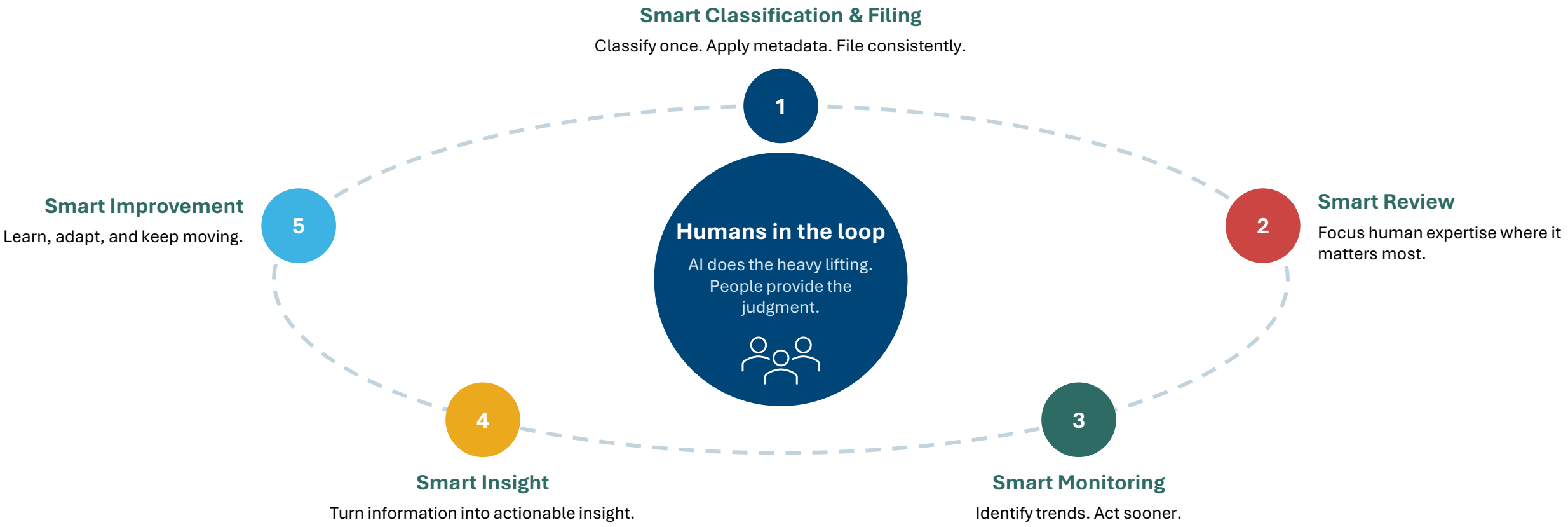
AI turns fragmented information into a clearer view of the terrain, helping support better decisions

https://www.clinicalresearchnewsonline.com/news/2026/06/18/moving-from-active-to-autonomous-tmf-with-agentic-ai

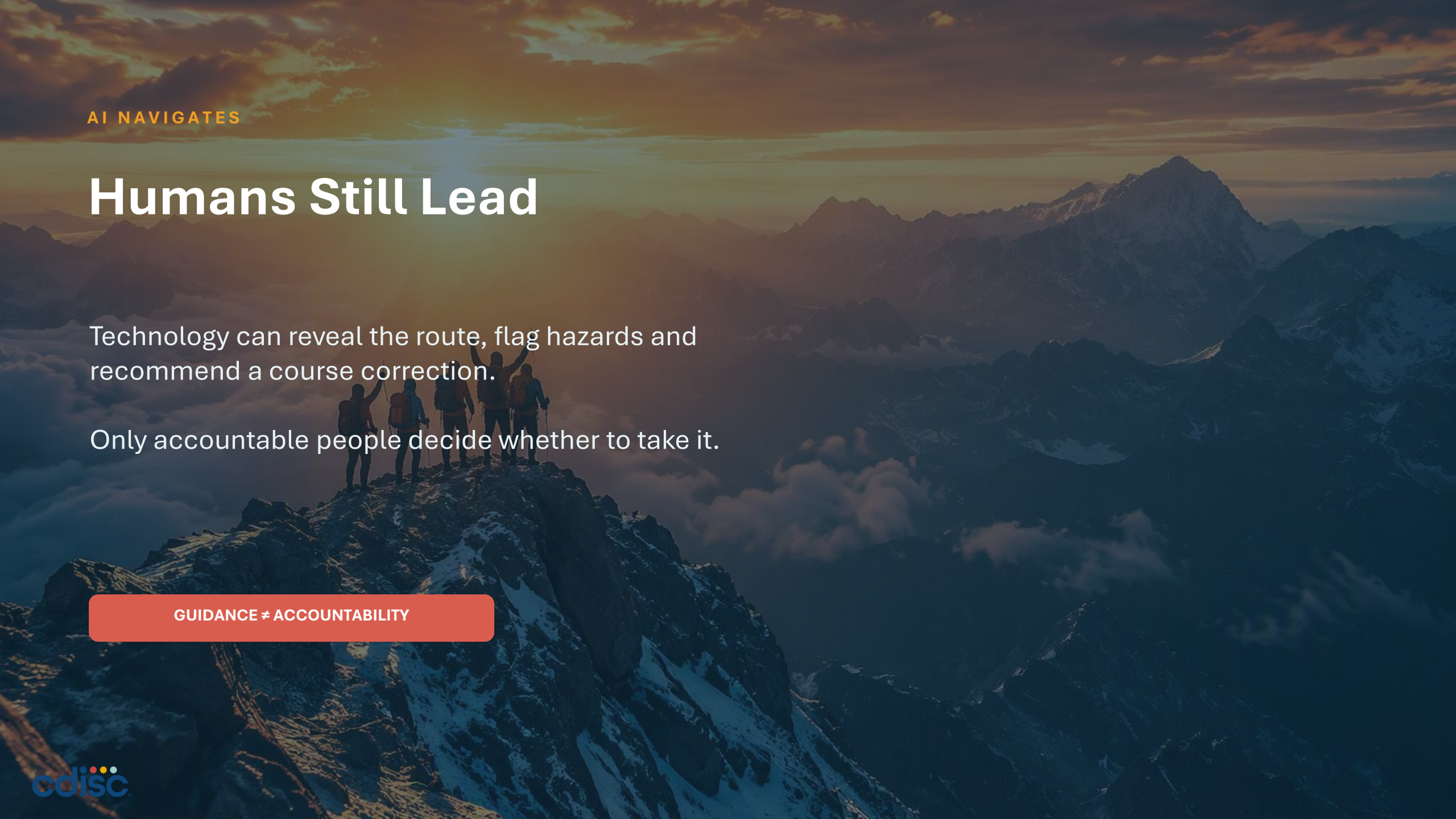
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Where AI Strengthens the Ascent

AI Tool with Humans in the Loop



Source: clinicalresearchnewsonline.com, "Moving From Active to Autonomous TMF with Agentic AI," June 2026



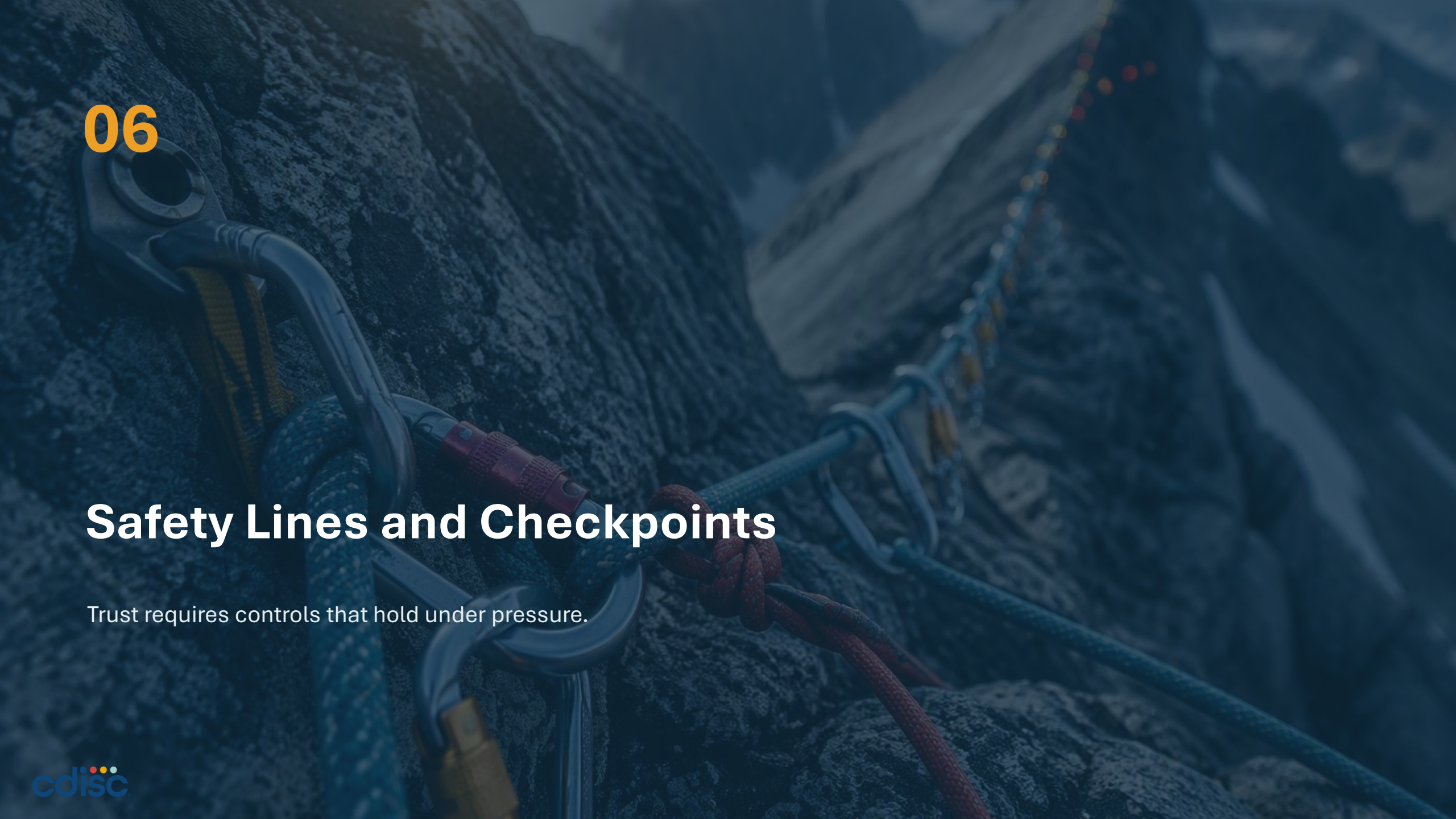
AI NAVIGATES

Humans Still Lead

Technology can reveal the route, flag hazards and recommend a course correction.

Only accountable people decide whether to take it.

GUIDANCE ≠ ACCOUNTABILITY



06

Safety Lines and Checkpoints

Trust requires controls that hold under pressure.

Building Trust Through Safety Checkpoints

Four Anchors for Trusted AI

Structured data

Consistent, standardized metadata

Complete accurate information

Quality checks at point of entry

Transparent logic

Clear intent and rules

Explainable outputs

Visibility into confidence and limitations

Traceability

End-to-end audit trail

Versioning

Evidence that stands up to inspection

Human oversight

Human review at defined decision points

Override and escalate as needed

Accountability remains with people

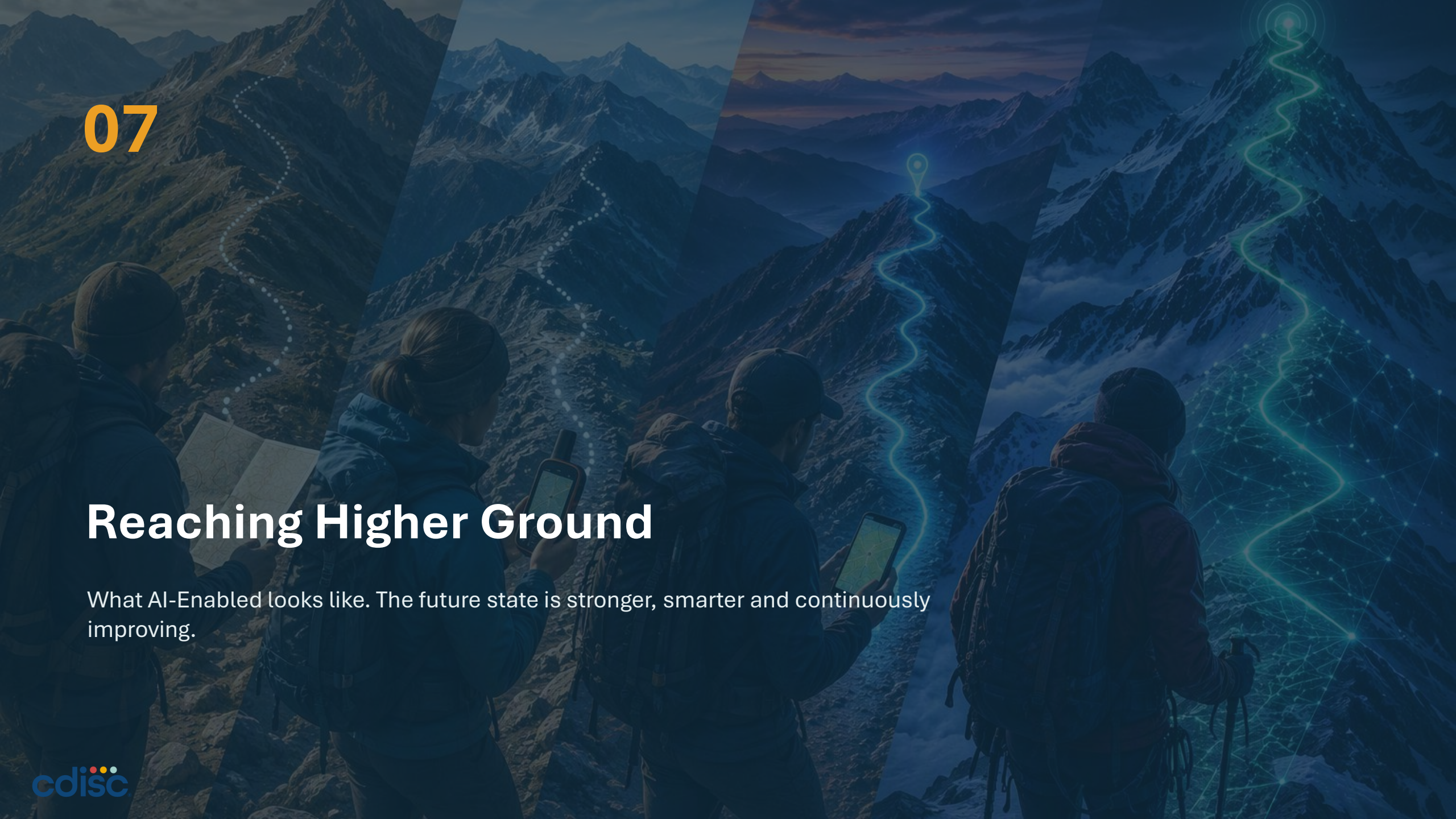
1 2 3 4

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07

Reaching Higher Ground

What AI-Enabled looks like. The future state is stronger, smarter and continuously improving.



A SMARTER, STRONGER TMF

Reaching the Summit

Four outcomes that turn AI-enabled capability into lasting TMF performance.

01

QUALITY AT THE CORE

Fewer errors • Consistent metadata • Stronger compliance • Inspection-ready

02

EFFICIENCY THAT MATTERS

Faster filing • Less rework • More time for high-value work

03

VISIBILITY THAT GUIDES

Real-time dashboards • Earlier risk detection • Clear insights for better decisions

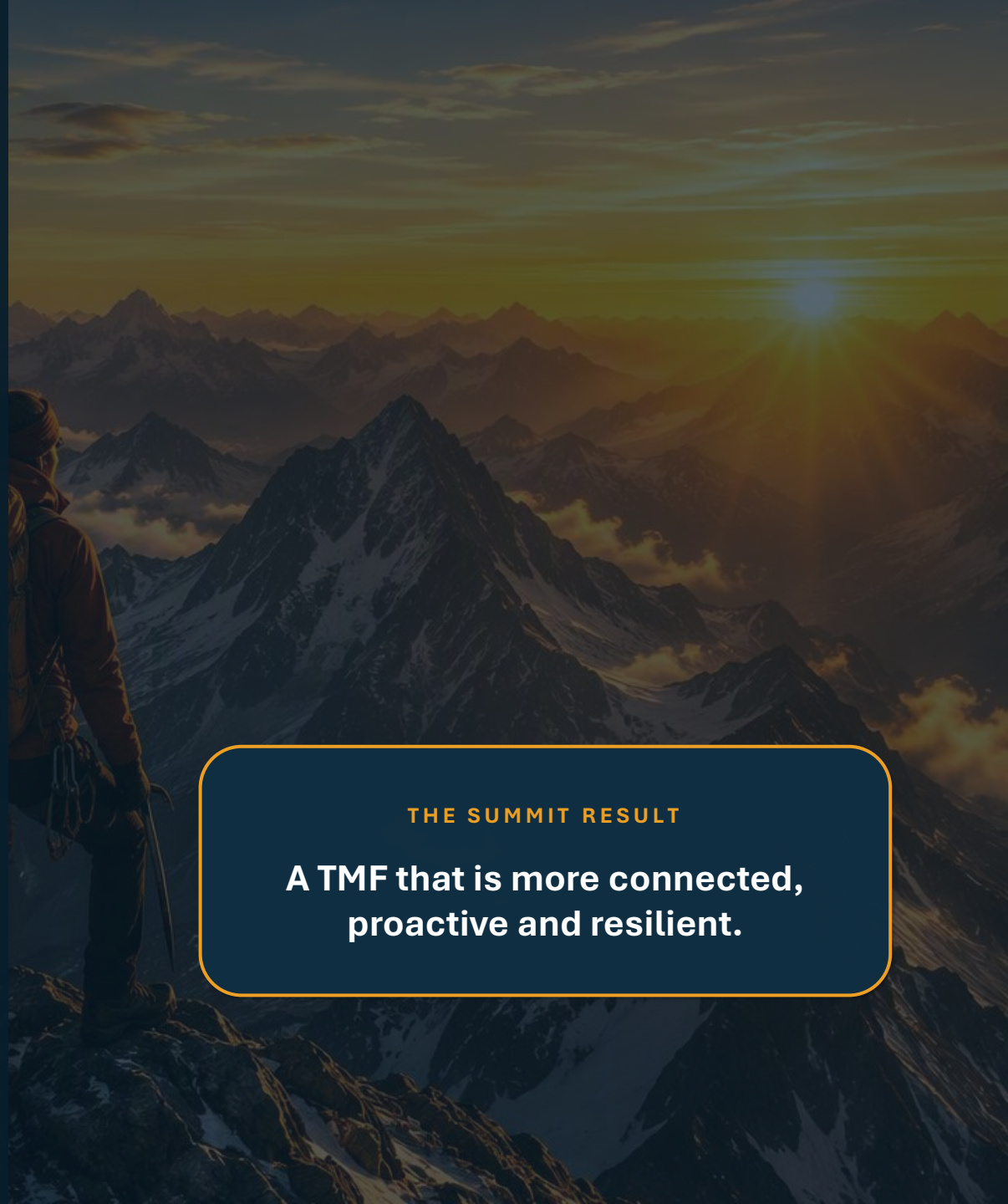
04

CONTINUOUS IMPROVEMENT

Learn and adapt • Improve process • Better outcomes over time

Same destination. Greater confidence on every climb.

Source: Clinical Research News, “Moving From Active to Autonomous TMF with Agentic AI,” June 2026



THE SUMMIT RESULT

A TMF that is more connected, proactive and resilient.

CAPABILITIES WE MAINTAIN

Continue to Raise the Bar for TMF Excellence

OUR FIVE COMMITMENTS

People
Expertise, ownership, and accountability

Process
Standardize, simplify, continuously improve

Data
Quality and consistency that enable good decisions

AI & Technology
Real value, right controls, humans in the loop

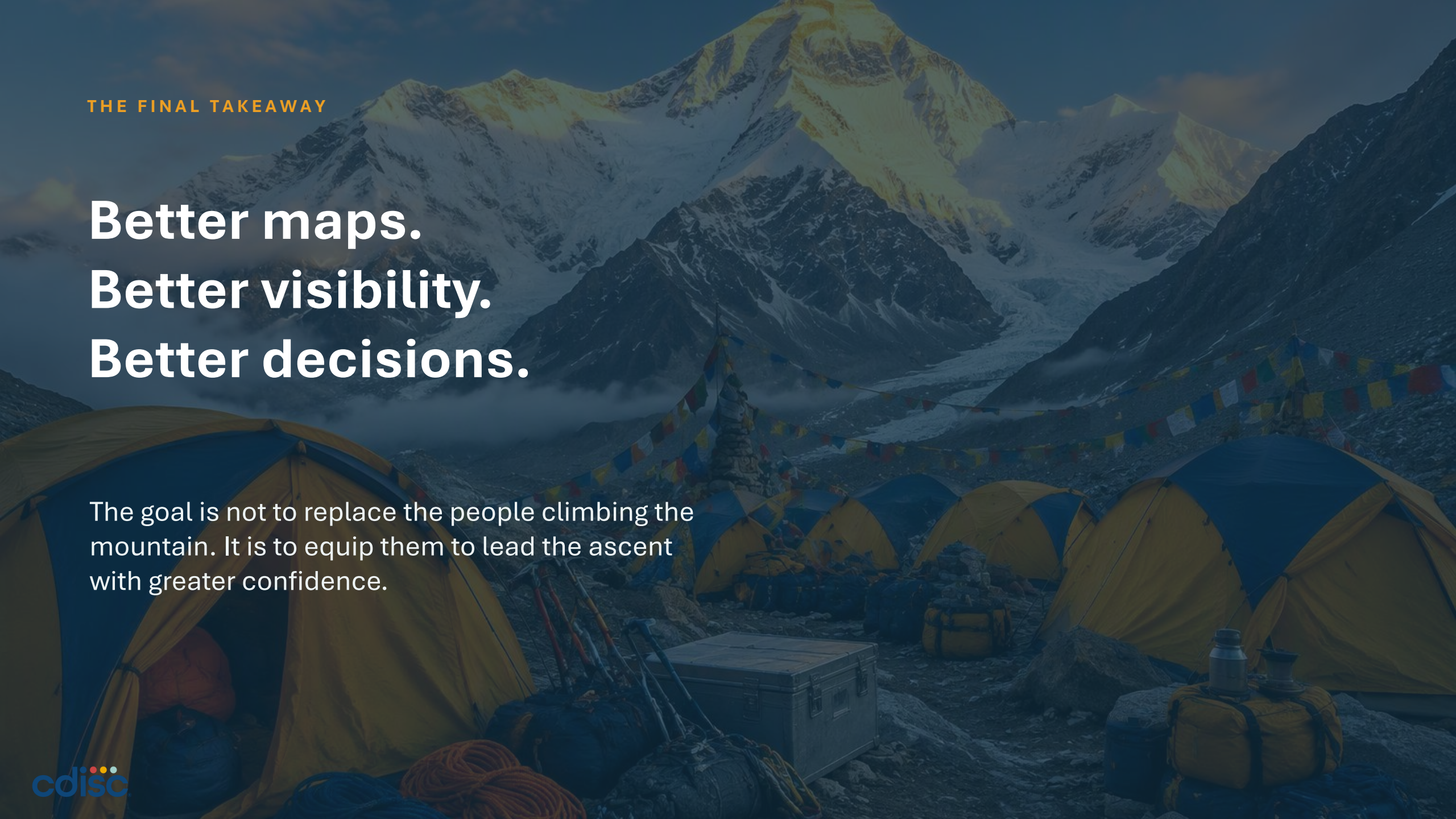
Partnership
Same destination, clearly defined roles



Not destinations we reach once — capabilities we maintain for every climb ahead

Informed by: CDISC, Trial Master File Reference Model / TMF Standard; EMA, “Reflection paper on the use of artificial intelligence in the medicinal product lifecycle,” September 2024; FDA, draft guidance on AI to support regulatory decision-making, January 2025

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THE FINAL TAKEAWAY

Better maps.
Better visibility.
Better decisions.

The goal is not to replace the people climbing the mountain. It is to equip them to lead the ascent with greater confidence.

QUESTIONS

What does the next stage of your TMF expedition look like?

Thank you

Christina Allen • Angie Gill

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