

2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Moving to a Standard and Beyond

TMF Standard Model V1 as the foundation for a connected, evidence-driven future

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Chair CDISC TMF Standard Model

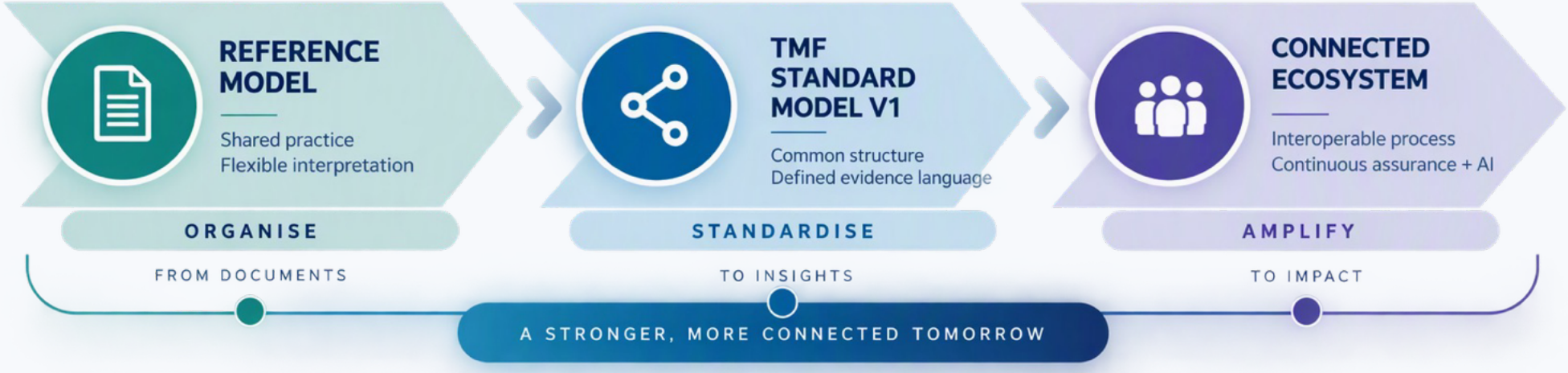
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STANDARDS.
BRIGHTER
HEALTHIER LIVES.

MOVING TO A STANDARD AND BEYOND

The story in one sentence

V1 creates the common language...
The next era connects evidence, process, quality and intelligence.



The shift is from organising files to controlling and explaining evidence.

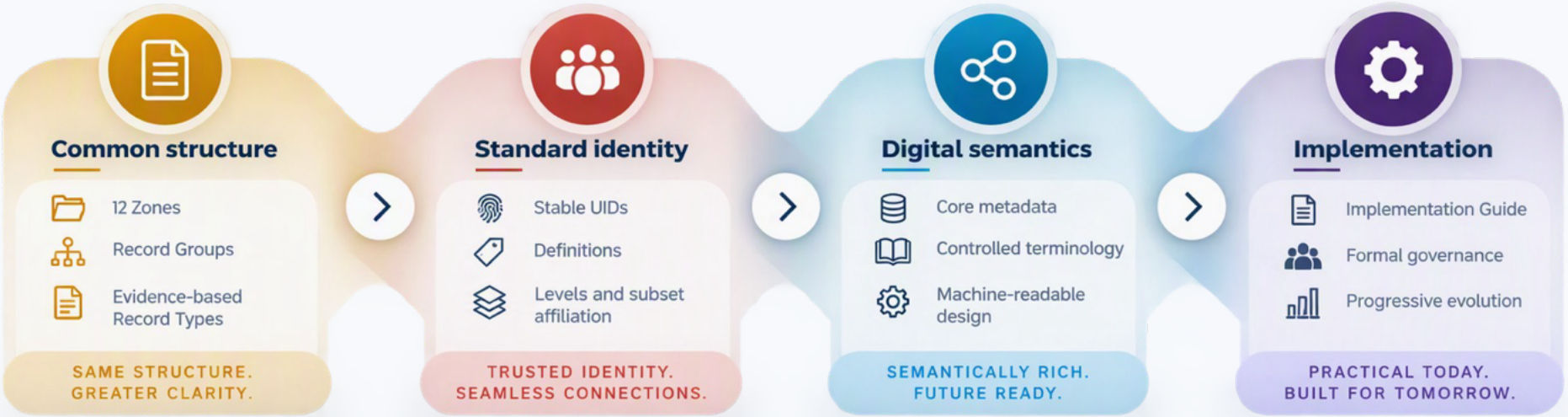
STANDARDS TODAY.
BRIGHTER TOMORROW.

HIGHER QUALITY STUDIES | GREATER COLLABORATION | HEALTHIER LIVES

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What V1 establishes

A governed, digital-ready foundation for essential study evidence.



ONE FOUNDATION • MULTIPLE USE CASES

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What we deliberately did not try to finish in V1

A strong standard needs a credible first release, not a "big bang".

V1
A stable core

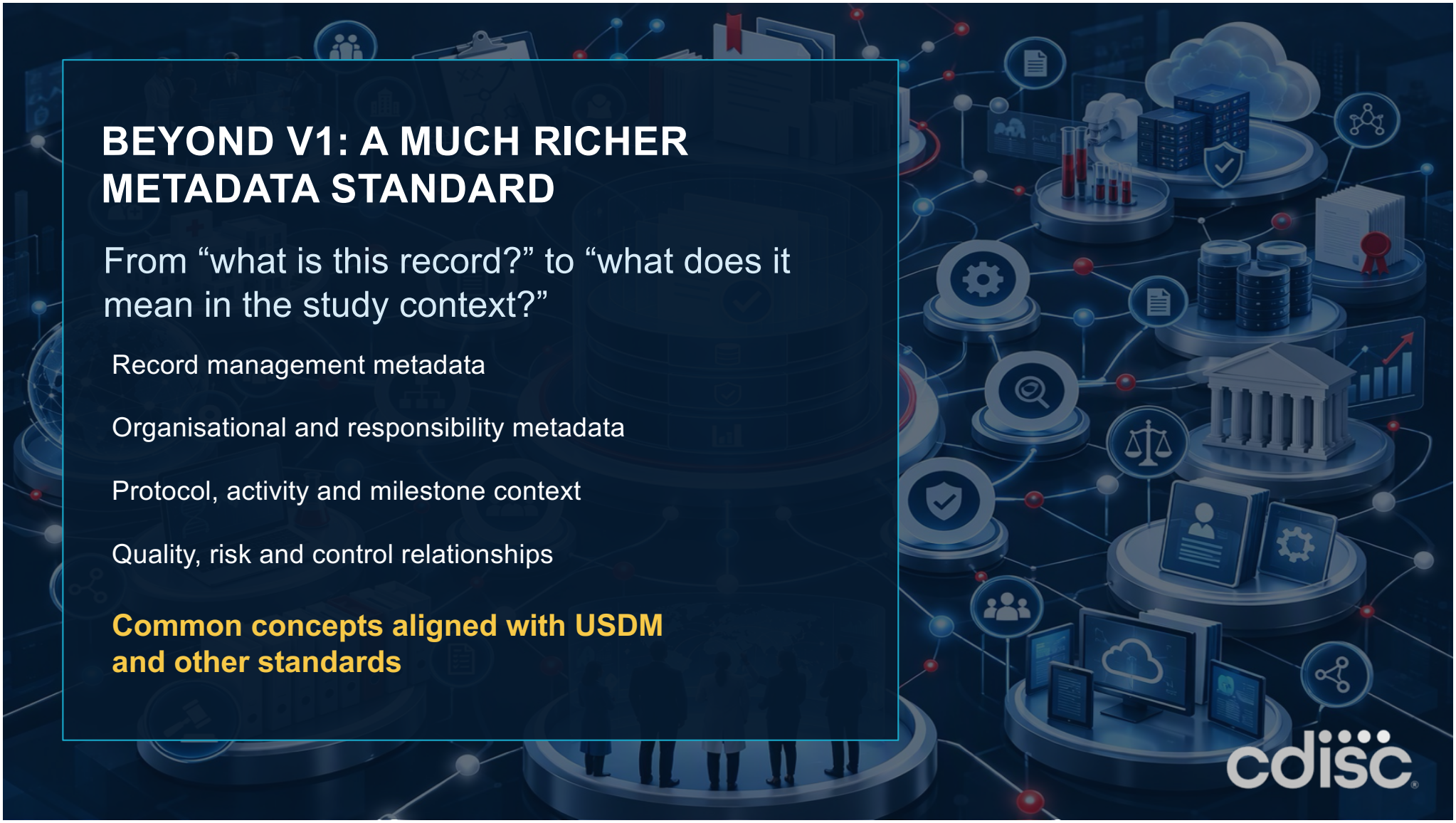
Metadata	Core identification first; richer operational and contextual metadata later.	**Future opportunity** Richer insights and traceability as experience grows.
Regionalisation	Global foundation first; governed regional views and extensions later.	**Future opportunity** Alignment with regional requirements and regulatory guidance.
Process model	Evidence taxonomy first; process and milestone integration later.	**Future opportunity** Validation with use cases and enable broader system integration.
Automation	Machine-readable foundation first; AI-supported compliance at scale later.	**Future opportunity** Build on real-world adoption and advances in AI capability.

FOCUSED TODAY. A STRONGER TOMORROW.

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BEYOND V1: A MUCH RICHER METADATA STANDARD
From “what is this record?” to “what does it mean in the study context?”
Record management metadata
Organisational and responsibility metadata
Protocol, activity and milestone context
Quality, risk and control relationships
Common concepts aligned with USDM and other standards
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Interoperability: connect the clinical study story

The TMF standard becomes a semantic bridge, not another isolated taxonomy.



Greater efficiency
Less duplication, more value

Improved transparency
Clearer oversight and traceability

Stronger collaboration
Across functions, organizations and geographies

Better outcomes
High-quality studies that make a difference

CDISC TMF STANDARD MODEL

A COMMON LANGUAGE THAT CONNECTS

Shared identifiers
Connects information across systems

Controlled terminology
Consistent, precise and scalable

Mapped concepts
Bridges different data sources

Exchangeable metadata
Enables reuse and future inoferation


GLOBAL STANDARD.
REGIONAL INTELLIGENCE.
Regionalisation without fragmentation
Governed regional subsets
Regional regulatory and language context
Local implementation guidance
Two-way feedback into the global core
Principle: specialise the view, not the underlying truth.
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A Federated Community Model

Scale participation, deepen expertise and bring regulators closer to the work.

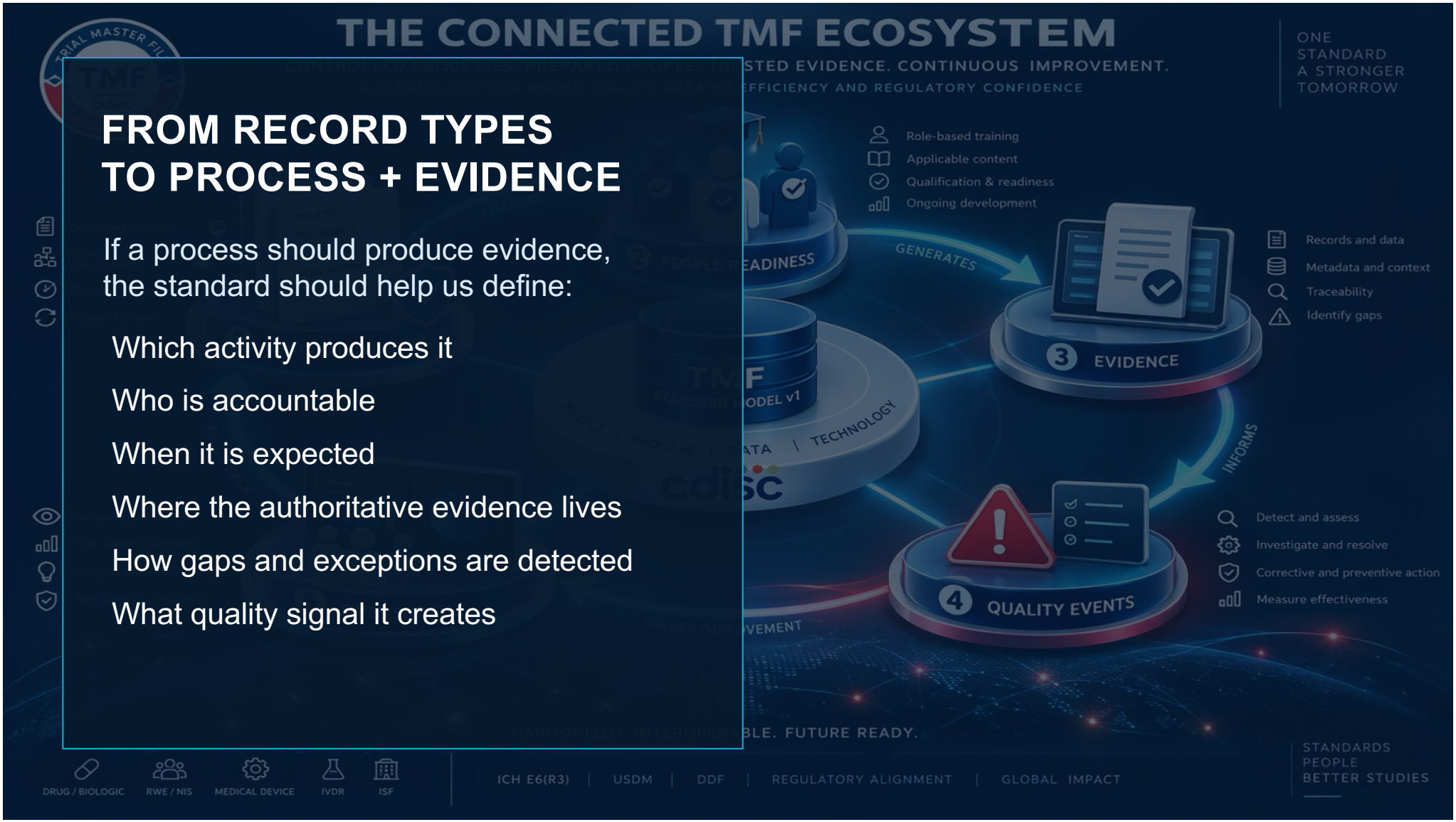


A STRONGER, MORE CONNECTED ECOSYSTEM

WIDER PARTICIPATION | DEEPER EXPERTISE | GREATER EFFICIENCY | BETTER OUTCOMES

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BRIGHTER TOMORROW.

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FROM RECORD TYPES TO PROCESS + EVIDENCE

If a process should produce evidence, the standard should help us define:

- Which activity produces it
- Who is accountable
- When it is expected
- Where the authoritative evidence lives
- How gaps and exceptions are detected
- What quality signal it creates

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MOVING TO A STANDARD AND BEYOND

A stronger bridge to Quality Assurance

Connected data. Shared meaning. Better decisions. A healthier tomorrow.



CDISC TMF STANDARD MODEL

A COMMON LANGUAGE THAT CONNECTS

SHARED IDENTIFIERS
Link information across systems

CONTROLLED TERMINOLOGY
Consistent, precise and scalable

MAPPED CONCEPTS
Bridges different data sources

EXCHANGEABLE METADATA
Enables reuse and innovation

STANDARDS TODAY.
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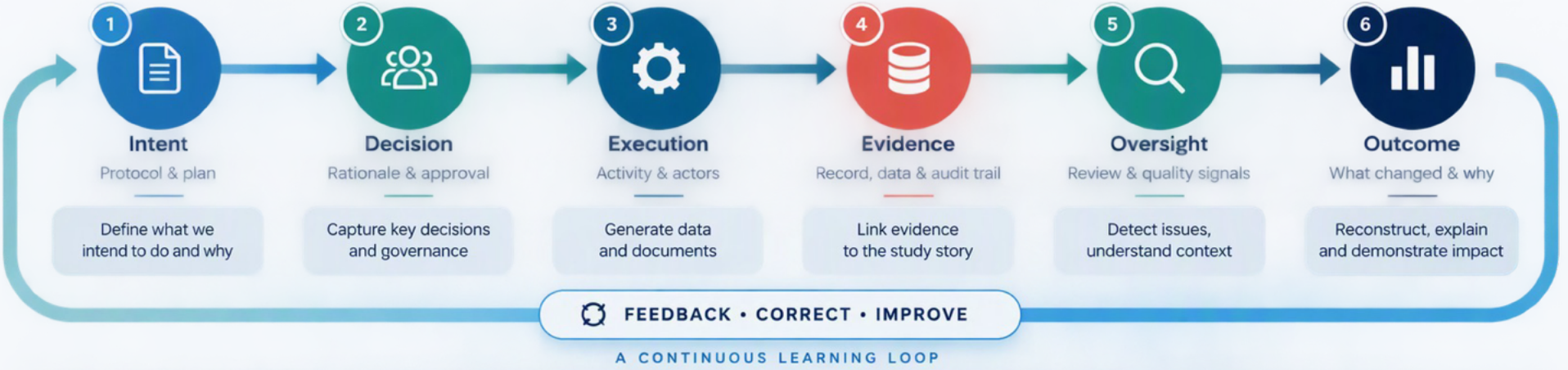
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MOVING TO A STANDARD AND BEYOND

Better storytelling: reconstruct the study, not the folder tree

Inspection readiness becomes the ability to explain the evidence chain on demand.



METADATA SUPPLIES THE RELATIONSHIPS

SHARED IDENTIFIERS
Link information across systems

CONTROLLED TERMINOLOGY
Consistent, precise and scalable

MAPPED CONCEPTS
Connect evidence across domains

EXCHANGEABLE METADATA
Enables reuse and innovation

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AI CAN EMPOWER COMPLIANCE WHEN THE STANDARD SUPPLIES TRUST

Find	Retrieve the right evidence across systems
Explain	Assemble the evidence chain and context
Detect	Surface gaps, inconsistencies and emerging signals
Guide	Bring applicable requirements into the flow of work
Learn	Use outcomes to improve controls and future execution

Human-governed • risk-proportionate • traceable • validated for intended use



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MOVING TO A STANDARD AND BEYOND

A practical horizon

Build outward from the stable core, with community validation at every step.



NOW

Publish + adopt V1

- Core structure
- Record Types
- Implementation Guide

ESTABLISH THE FOUNDATION



NEXT

Enrich meaning

- Expanded metadata
- USDM alignment
- Regional subsets

BROADEN UNDERSTANDING



THEN

Connect operations

- Process + milestones
- Evidence federation
- QA integration

ENABLE AT SCALE



HORIZON

Intelligent assurance

- AI-supported story
- Continuous signals
- Proactive compliance

REALIZE LASTING IMPACT

Not a single project. A governed programme of evolution.

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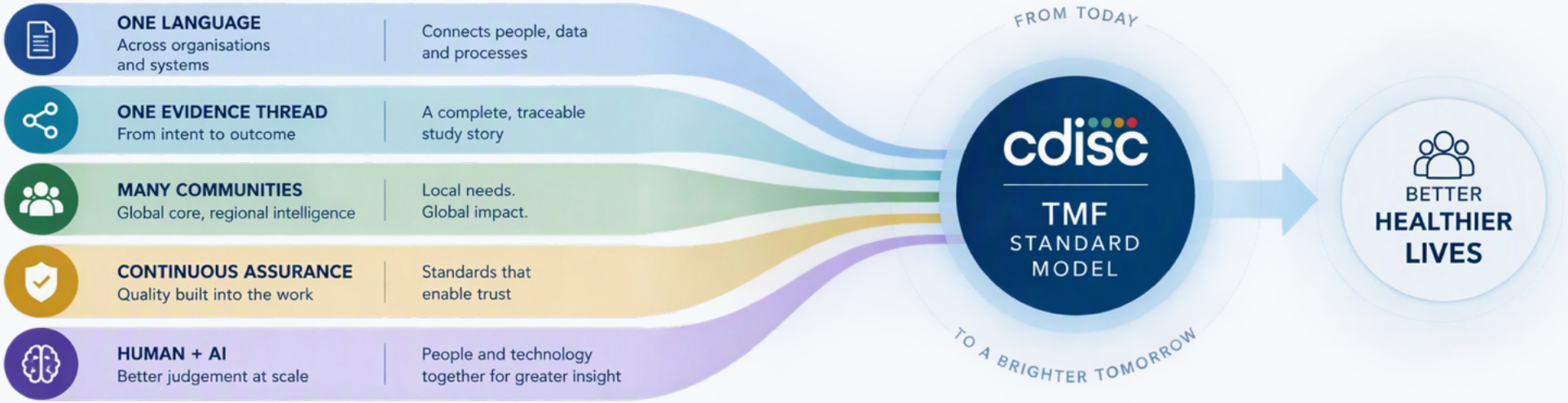
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MOVING TO A STANDARD AND BEYOND

The future we are building

A standard that helps people find, understand, trust and improve the evidence of clinical research.



V1 is the moment we **move to a standard.** | What comes next is **how** the **standard** moves the industry. →

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What should the TMF Standard Model make possible next?