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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Beyond the Repository
Harmonising TMF Ecosystems through Interoperability and Data Flow

Ricky Lakhani, Chief Product Officer, PHARMASEAL

Meet the Speaker

Ricky Lakhani

Chief Product Officer

PHARMASEAL

Ricky Lakhani is the Chief Product Officer at PHARMASEAL, where he leads the strategic development and innovation of the Engility® trial management platform. With over 20 years of experience at the intersection of life sciences and technology, Ricky is a recognised expert in delivering scalable, user-focused software solutions that streamline clinical trial execution and oversight. He has held senior product leadership and management roles at prominent global organisations, including Amgen, Roche, and Medidata. His expertise spans the full clinical data lifecycle, with a specific focus on breaking down functional silos through unified digital architectures, robust interoperability standards, and the integration of eTMF, CTMS, and archival solutions.

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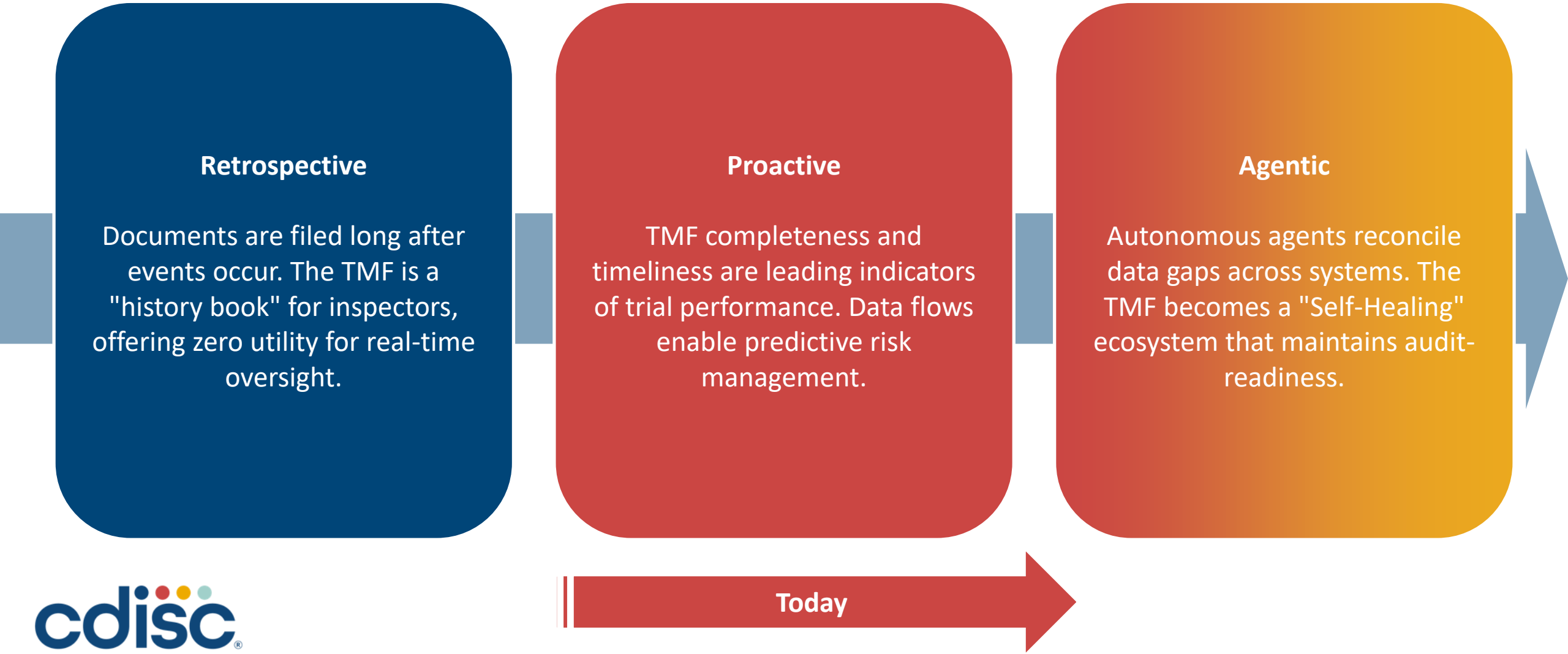
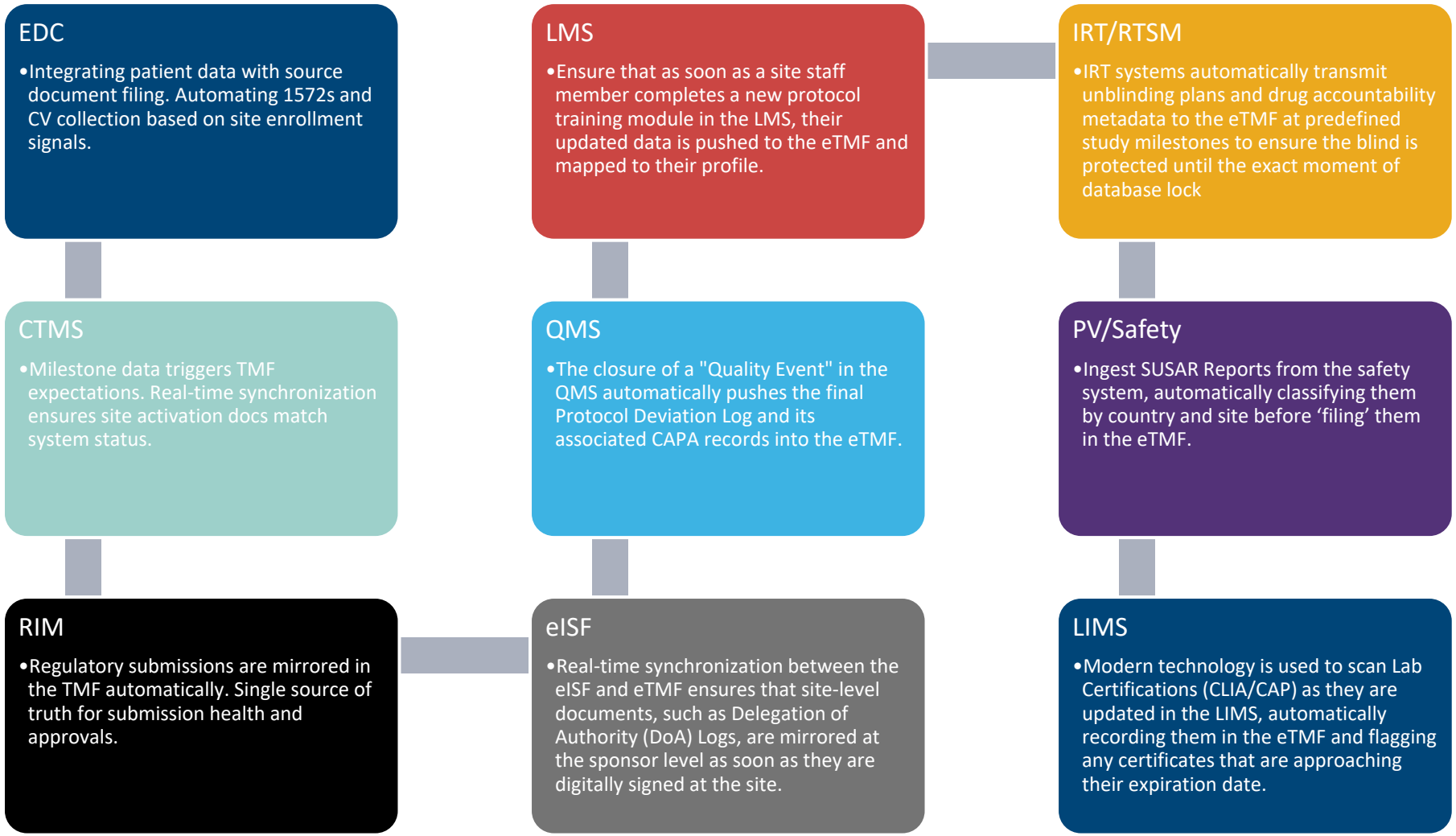
The eTMF is the Pulse of Clinical Trial Health

Transitioning from retrospective storage to a living, breathing study management command center.

The evolution of TMF maturity



Bridging the systems divide



...and more…

FDA & EMA: AI Metadata Expectations

The guiding principles

Human-in-the-Loop
Integrating patient data with source document filing. Automating 1572s and CV collection based on site enrollment signals.

Data Provenance
Clear audit trails must show where AI-generated metadata originates from and which model version was used.

Explainability
Black-box models are discouraged; regulators demand rationale for auto-classification

Validation
Ongoing performance monitoring (drift detection) is mandatory to ensure algorithm accuracy over the trial life cycle.

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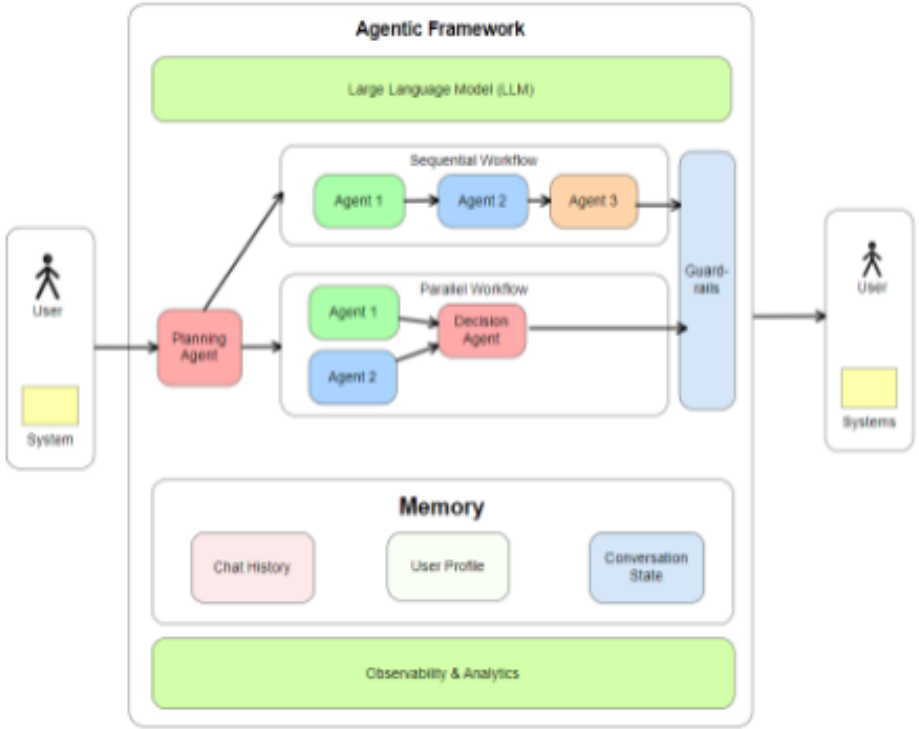
Agentic AI: Action-oriented TMF

Specific eTMF Use Cases

Autonomous Reconciliation
Agents cross-check CTMS visit reports against eTMF documents, flagging missing files before the visit is closed.

Self-Healing Metadata
Automatically correcting minor naming convention errors and tagging missing mandatory fields.

Intelligent Site Triage:
Analyzing site-specific filing patterns and autonomously sending reminders for specific missing certifications.



Single vendor vs. Multi-vendor

Single Vendor

- Streamlined technical support
- Unified data model (no mapping)
- Lower IT integration overhead
- Potential “feature lag” in specific modules

The Interoperable Hybrid

Bridging the gap using Modern APIs and Agentic Orchestration layers to ensure data integrity across specialized systems.

Multi-Vendor

- Best-of-Breed functional depth
- No vendor lock-in
- Increased operational flexibility
- Requires robust interoperability standards

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Re-engineering business processes

The “Human” Shift

From Filer to Manager:
Empowering TMF teams to handle data flows and exception management rather than document uploads.

Cross-Functional Ownership
ClinOps, Reg, and Data Management must own their data feeds into the TMF ecosystem.

Eliminating Shadow Trackers:
Replacing legacy Excel trackers with a single source of truth in the interoperable eTMF.

Reduction in Admin Burden
Observed when shifting from manual filing to AI-augmented oversight.

Reducing friction in transitions

Streamlined finalization

“Harmonized systems ensure that study close-out is a verification exercise, not a forensic search.”

Automated Handovers:
Instant transfer of audit-ready content from CRO to Sponsor systems via an industry-standard exchange format.

Migration Efficiency:
Mapping tools reduce the months typically lost in legacy system.

Risk Mitigation:
Finding gaps *during* the trial, not at the close-out peak.

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Interoperable TMF strategy roadmap

Questions?

Let’s build a TMF that breathes with your clinical trial.