

# From Manual to Seamless

Transforming Serious Adverse Event Reconciliation with Integrated Platforms

ACDM26 Berlin

Presenter: Theodora Velona

Senior Clinical Data Manager



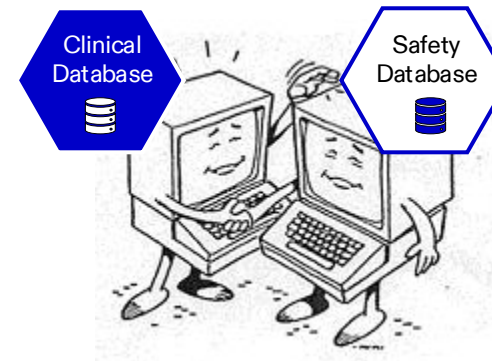
16-Mar-2026

# Disclaimer

**The opinions expressed here are my personal views and do not reflect the views or opinions of Pfizer, Inc.**

# What is Serious Adverse Event (SAE) Reconciliation?

- Serious Adverse Event (SAE) reconciliation is a process ensuring SAE data present in the study database and safety database(s) are appropriately clean, actionable, reliable, and prepared for statistical analysis and/or reporting.



# Why SAE Reconciliation Matters



- SAE reconciliation ensures alignment between EDC and safety systems.
- Critical for patient safety and regulatory compliance.

# Why Traditional Reconciliation Is Still a Challenge

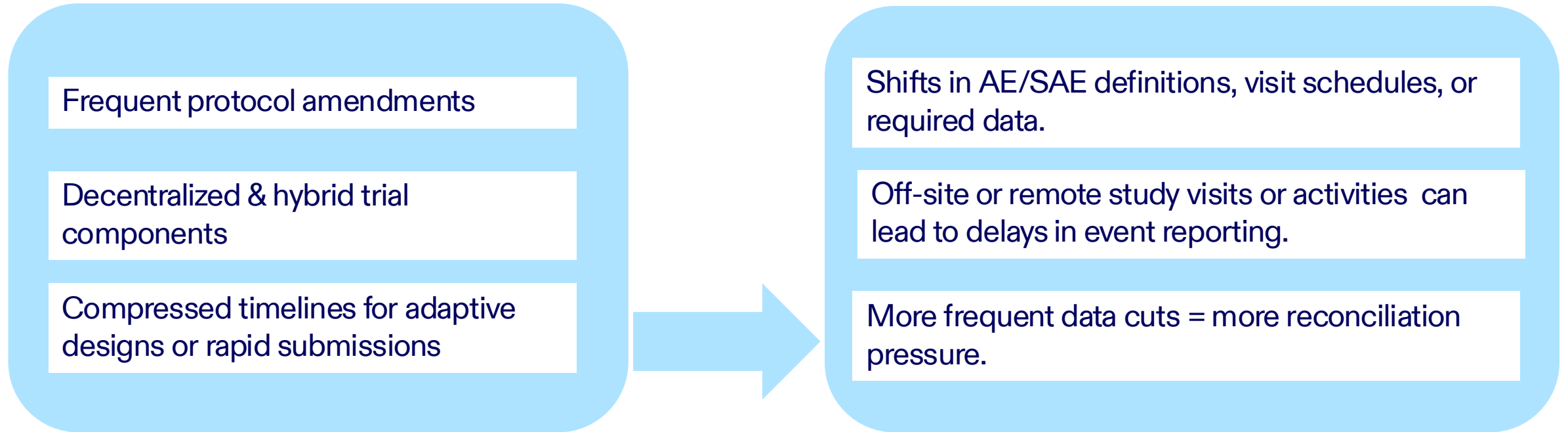
The current-state issues:

- Manual checks across two or more systems
- Late discovery of discrepancies
- Reliance on manual communications
- Delays approaching DBL or interim analyses
- Manual processes can contribute to challenges across studies/vendors



# Operational Complexities Affecting SAE Reconciliation Across Modern Trials

Evolving trial designs introduce new operational burdens



## Impact:

- ◆ Increased discrepancies
- ◆ Time-consuming manual oversight
- ◆ Higher risk of delayed issue detection
- ◆ Burden on PV and DM teams

# The Opportunity: Integrated Data Platforms (IDP)

What is an IDP?

An integrated platform in clinical research is a technology ecosystem that connects multiple clinical and safety data systems so they can exchange data automatically, consistently, and in a controlled way.

- ✓ An integrated platform is the connective tissue that ensures all systems “talk to each other” without relying on manual data transfer, or other manual communication methods (e.g., spreadsheets, or email chains).

# How systems talk to each other – Main Technologies used

APIs

Middleware / Integration Engines

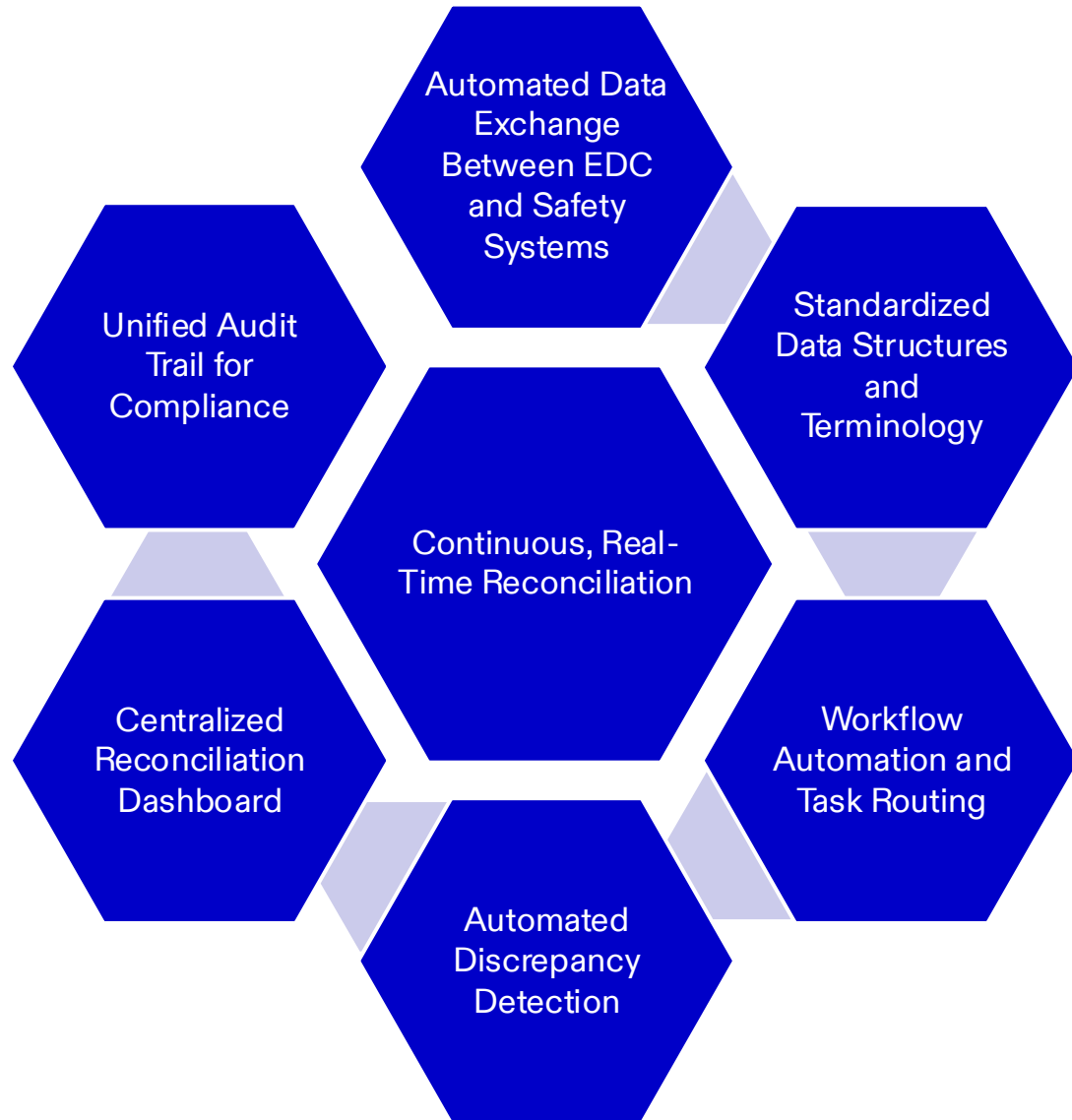
Direct Database Connections

Automated File-Based Exchanges (SFTP)

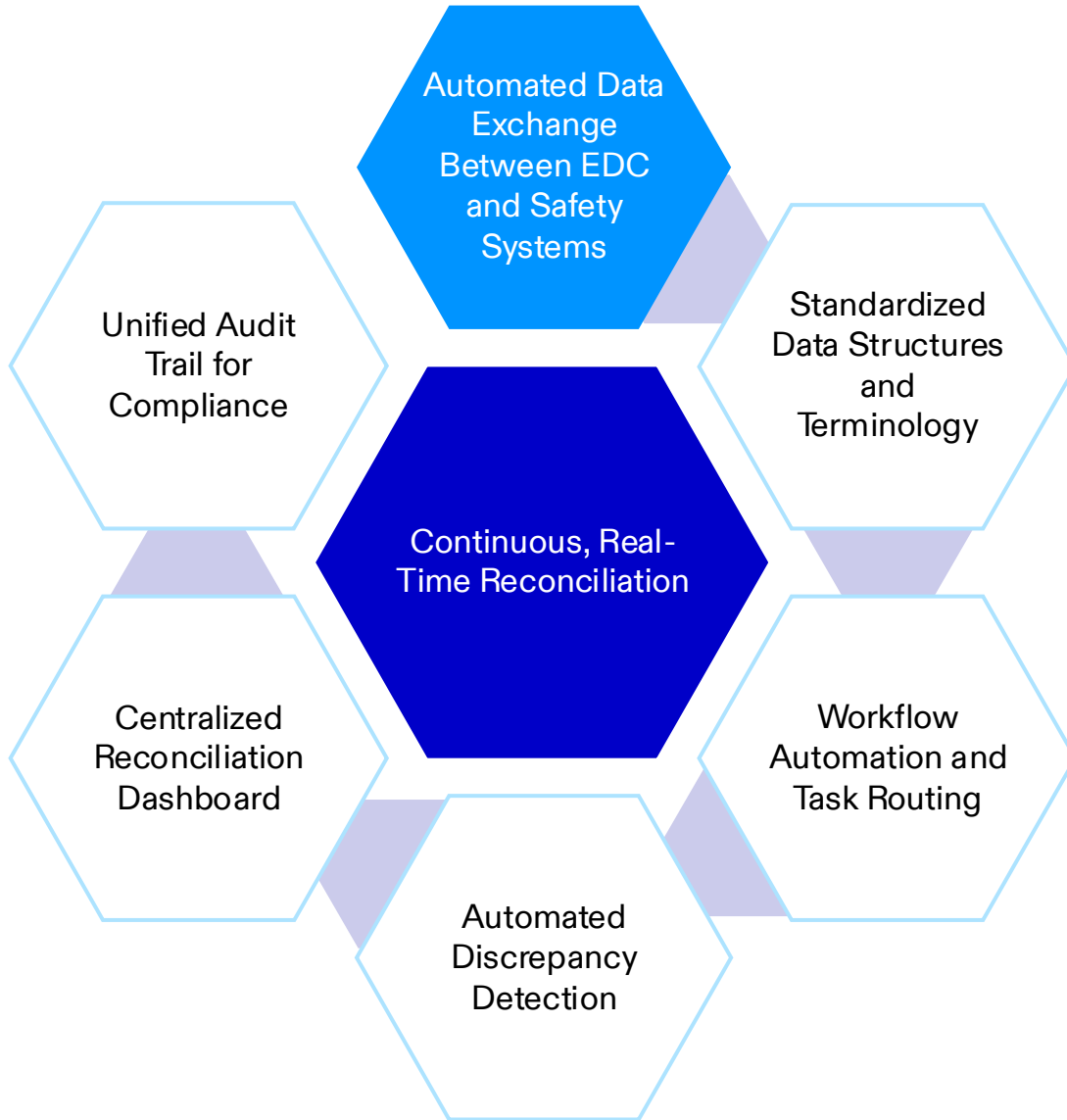
Event-Driven Messaging (Webhooks / Message Queues)

# How Integrated Platforms Function in the Context of SAE Reconciliation

# How Integrated Platforms Function in the Context of SAE Reconciliation

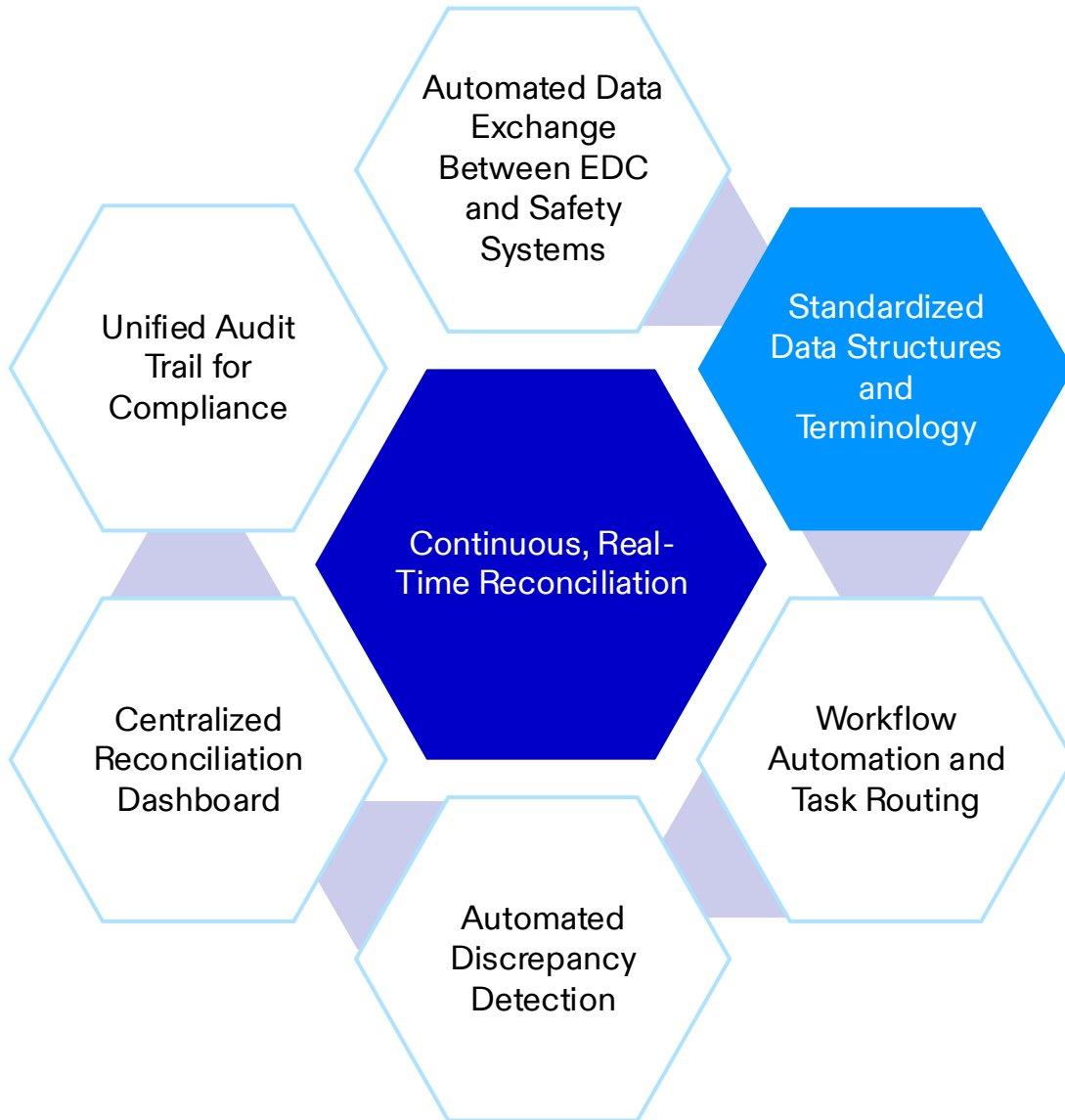


# How Integrated Platforms Function in the Context of SAE Reconciliation



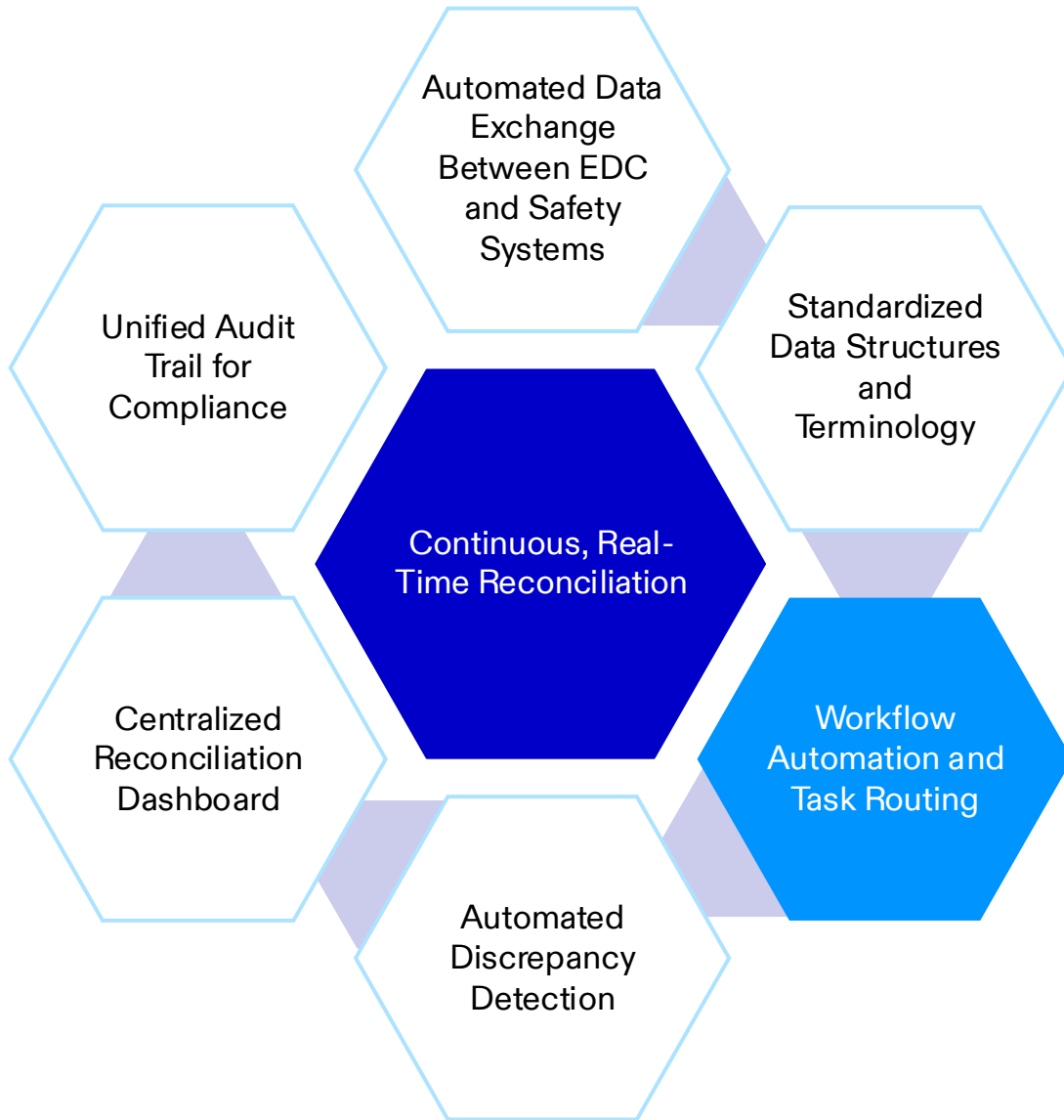
- ✓ SAE entries and updates in EDC are received automatically by safety system
- ✓ Systems remain aligned without manual re-entry

# How Integrated Platforms Function in the Context of SAE Reconciliation



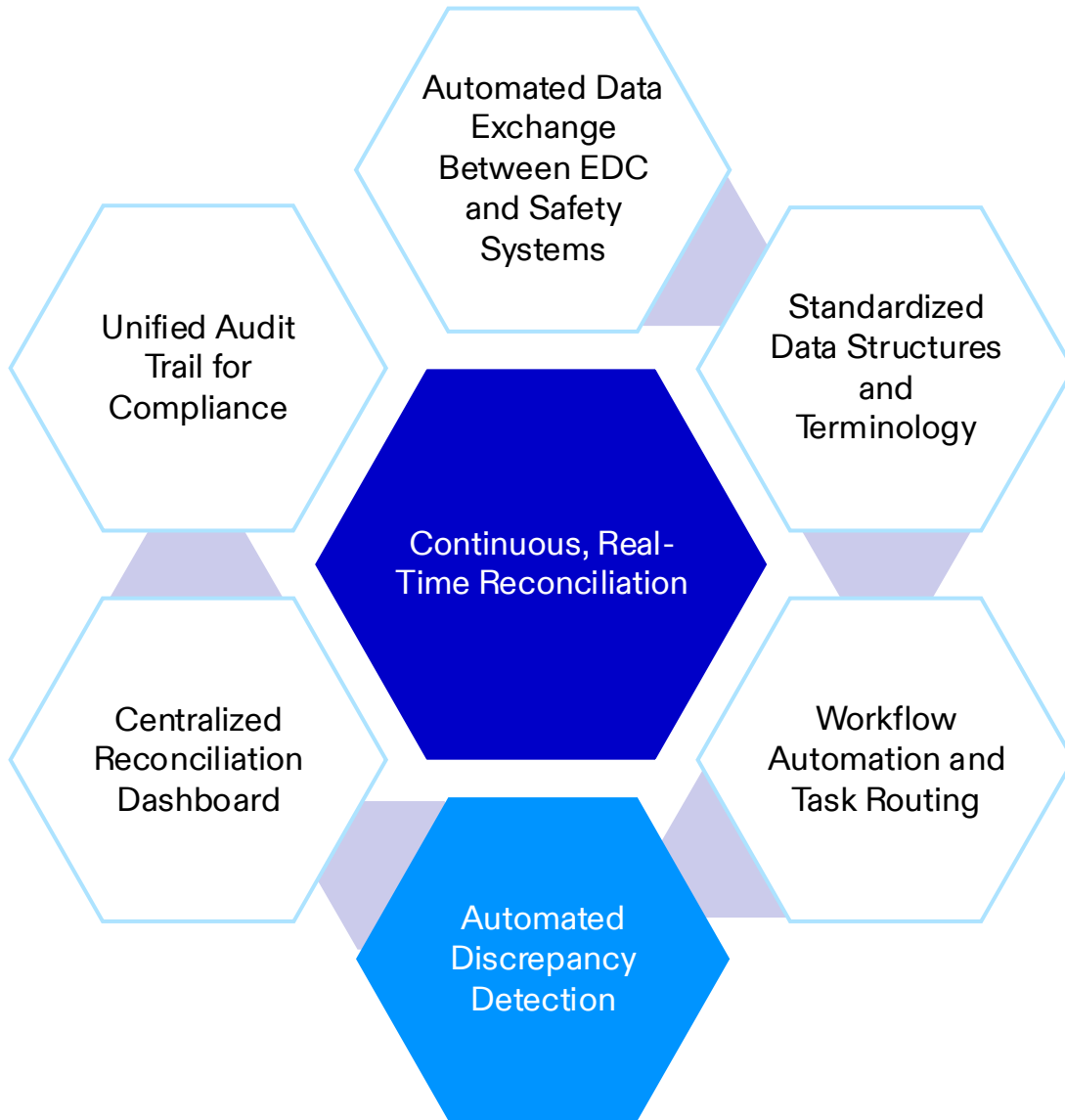
- ✓ Common industry standards (CDASH/CDISC, MedDRA) standards allow systems to “understand” meaning of data.
- ✓ Integrated platforms map fields between systems in a controlled way (SubjID, Dates (onset, resolution, reporting), Event terms (MedDRA), Seriousness criteria, Outcomes)

# How Integrated Platforms Function in the Context of SAE Reconciliation



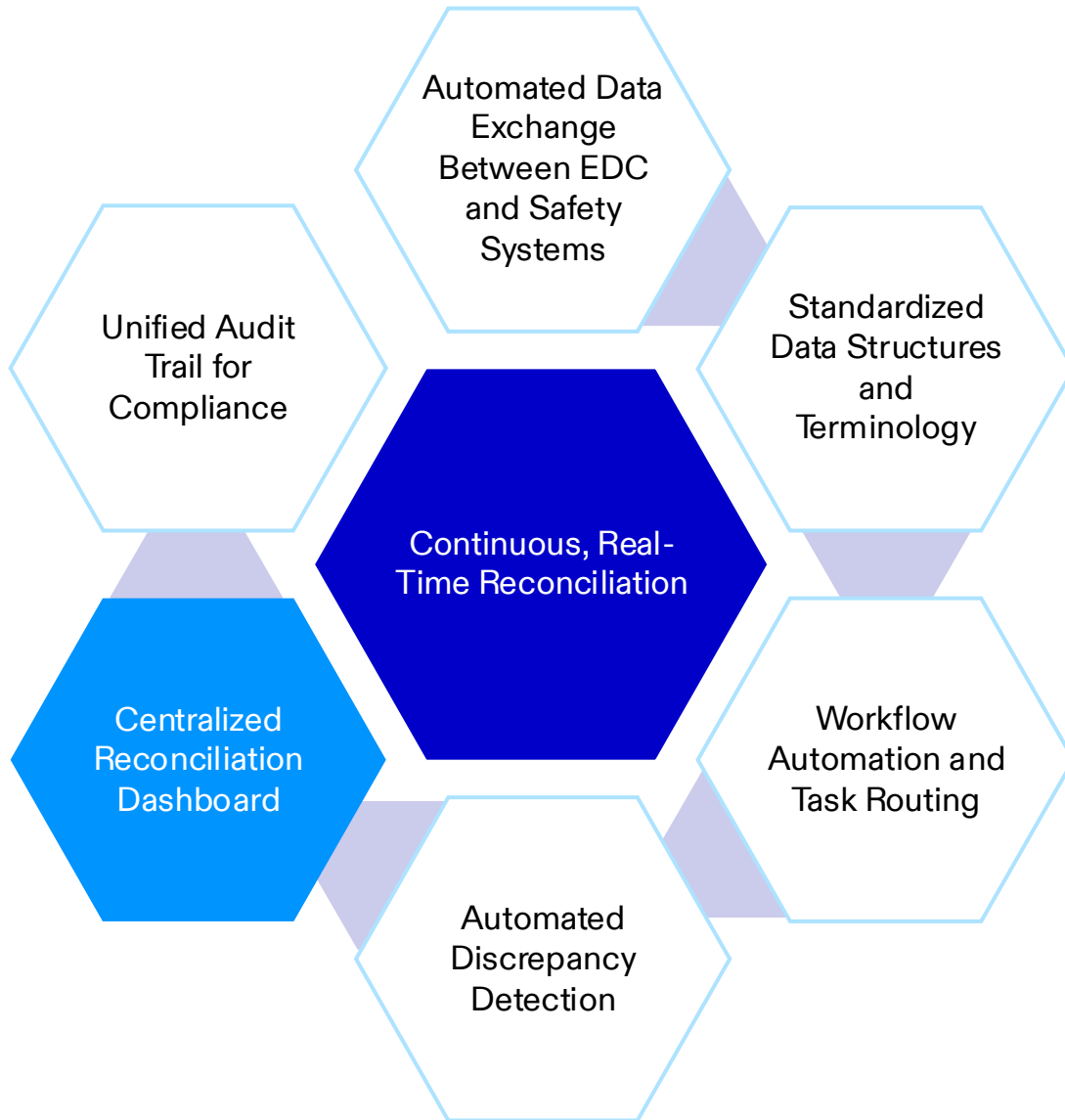
- ✓ System automatically sends tasks to the correct user or group
- ✓ Status updates are tracked
- ✓ Completed actions are recorded in the audit trail

# How Integrated Platforms Function in the Context of SAE Reconciliation



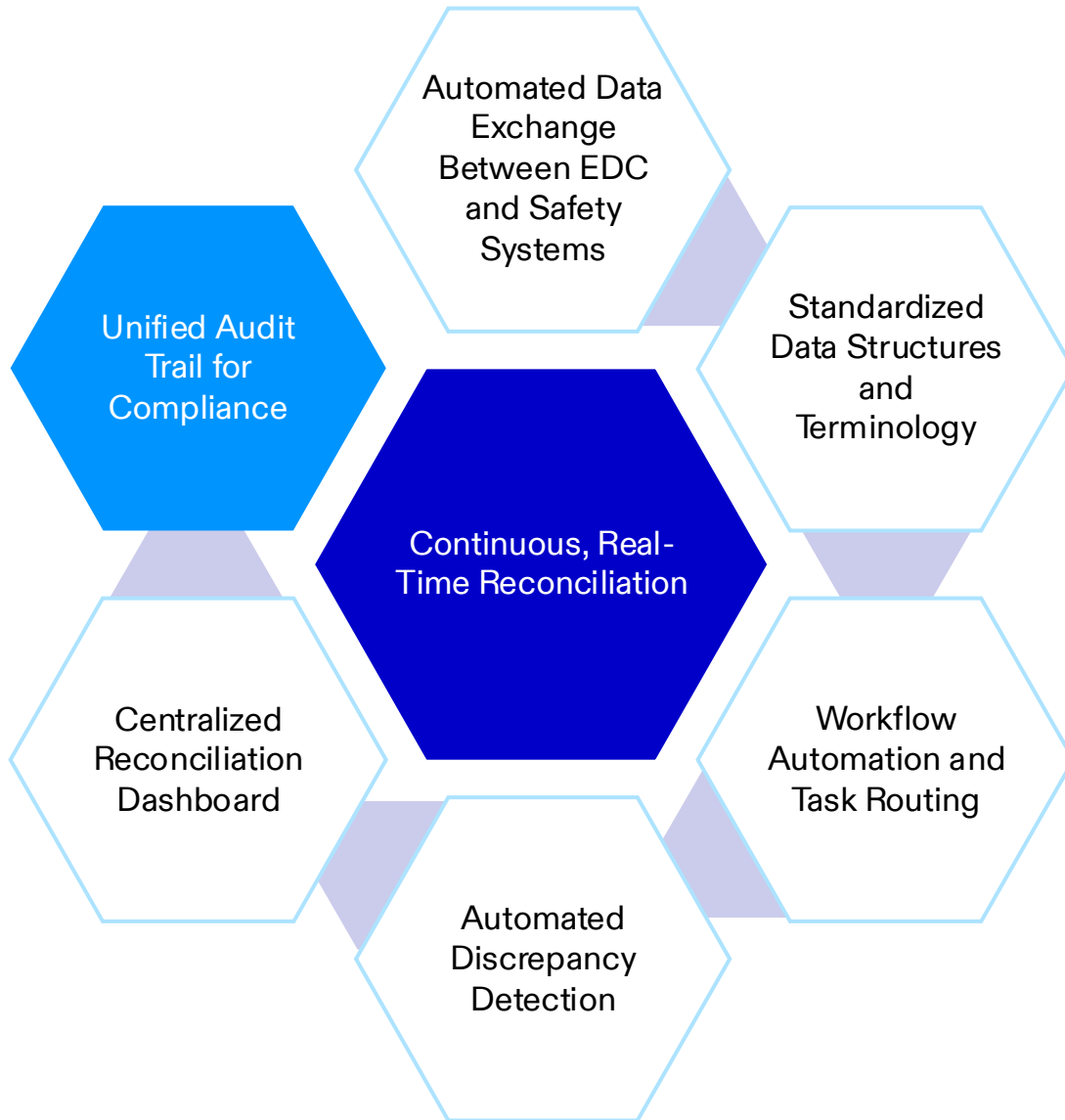
- ✓ Instead of manually checking every field, the platform applies predefined rules
- ✓ All discrepancies are automatically flagged, reducing human effort and turnaround time.

# How Integrated Platforms Function in the Context of SAE Reconciliation



- ✓ Integrated platforms typically provide a single view for DM and PV
- ✓ Replace scattered, de-centralized manual communications, e.g. excel trackers and email threads.

# How Integrated Platforms Function in the Context of SAE Reconciliation



✓ All reconciliation actions—data updates, queries, clarifications—are automatically logged.

- Inspection readiness
- Transparent oversight
- Consistent documentation

# Mini Workshop

For each scenario, decide: Automate or Escalate?

Missing or unclear hospitalization dates

Outcome mismatch (e.g., “not recovered” vs “recovered”)

Unexpected serious event requiring medical review

Partial updates made only in one system

Seriousness criteria differing between DM and PV entries

# Conclusion: Benefits of Integrated platforms in SAE reconciliation

Real-Time, Continuous Reconciliation

Automation of Routine Reconciliation Tasks

Cross-functional collaboration

Cross-Study and Portfolio-Level Intelligence



Multi-Source  
Data  
Harmonization



Readiness for  
Regulatory  
Automation



Leverage  
of AI



Risk-Based  
Reconciliation  
Strategies

**Emerging  
opportunities**

# Thank You

