2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION





The Clinical Study Data Flow Diagram

Liz Farrell, Sr. Director, Compliance and TMF Oversight , Agios Pharmaceuticals
Lisa Mulcahy, Owner, Principal Consultant, Mulcahy Consulting, LLC



Liz Farrell

Sr. Director, Compliance and TMF Oversight

Agios Pharmaceuticals

Liz Farrell is the Director, Compliance and TMF Oversight at Agios Pharmaceuticals, where she leads strategy and governance for the Trial Master File (TMF) and Functional Compliance oversight. In this role, Liz partners across clinical, quality, and operational functions to drive inspection eadiness, maintain regulatory compliance, and ensure excellence in TMF management and clinical documentation practices. With over 15 years of experience across TMF, Compliance, and Clinical Operations, she has implemented global eTMF systems, managed large-scale TMF migrations, and led teams supporting inspection readiness. Liz has also served as a TMF Subject Matter Expert in multiple regulatory inspections.



Lisa Mulcahy

Consultant in the areas of TMF Management and Clinical Computer System Assurance

Mulcahy Consulting, LLC

Lisa Mulcahy has an extensive 35 career in the biopharmaceutical industry in areas of Clinical Operations, Quality Management, and TMF Management. her expertise to support small-medium biotech companies to develop, revise, and operationalize high-quality and compliant electronic TMF management systems, processes, and resources to achieve complete and inspection-ready of TMFs and ensure process-driven documented oversight of clinical systems.

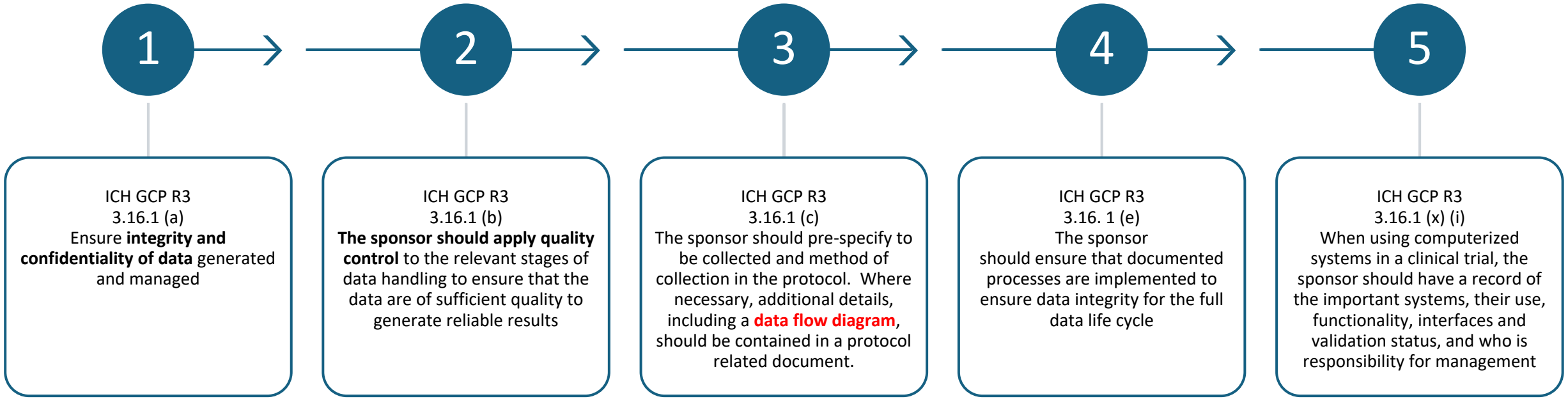
Lisa is a member of the management committee who are driving the transformation of the CDISC TMF Reference Model to the CDISC TMF Standard Model. She is a current CDISC TMF Community Steering Committee Member and a certified CDISC trainer who creates and delivers CDSIC TMF-related courses.

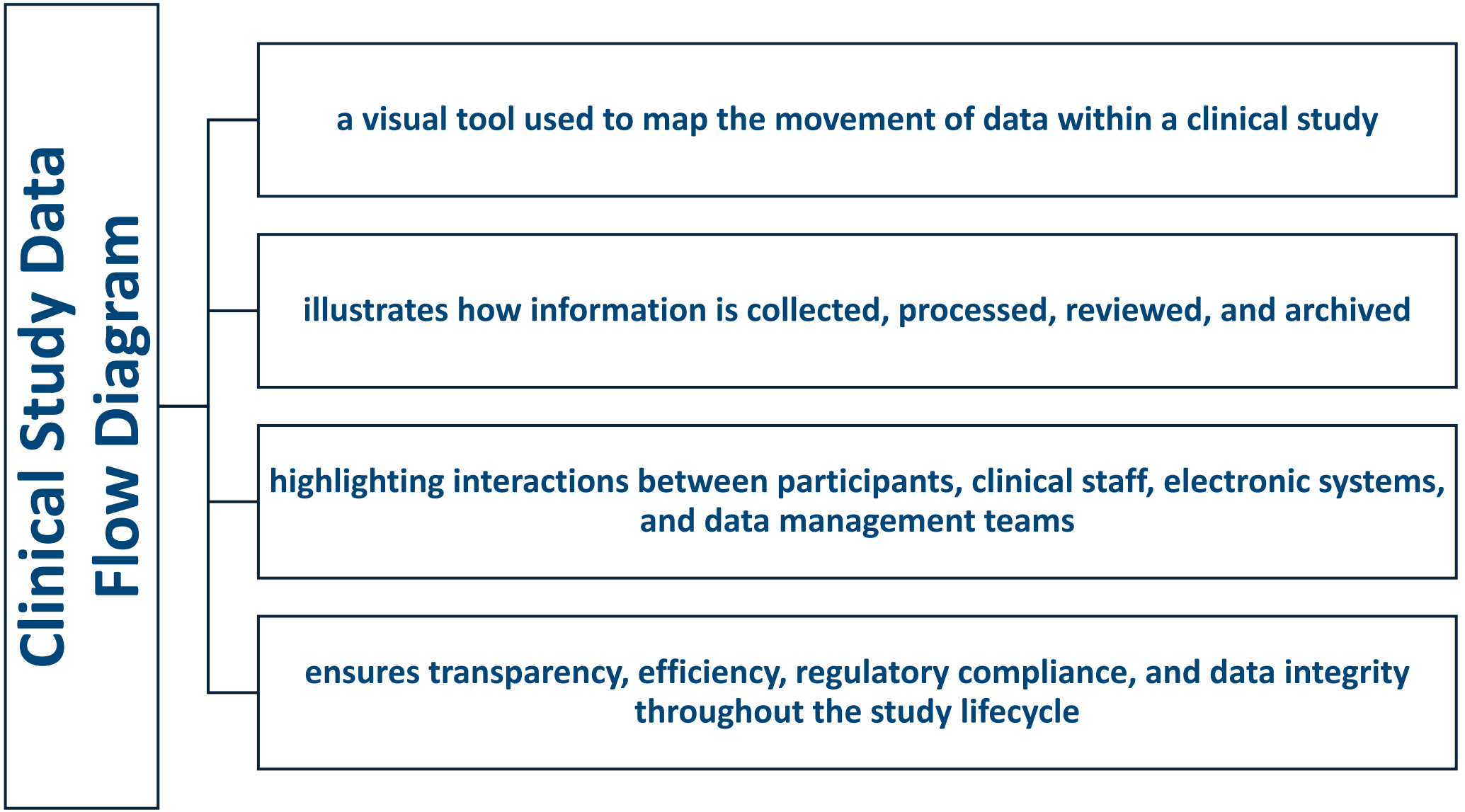
The Clinical Study Data Flow Diagram

The basics

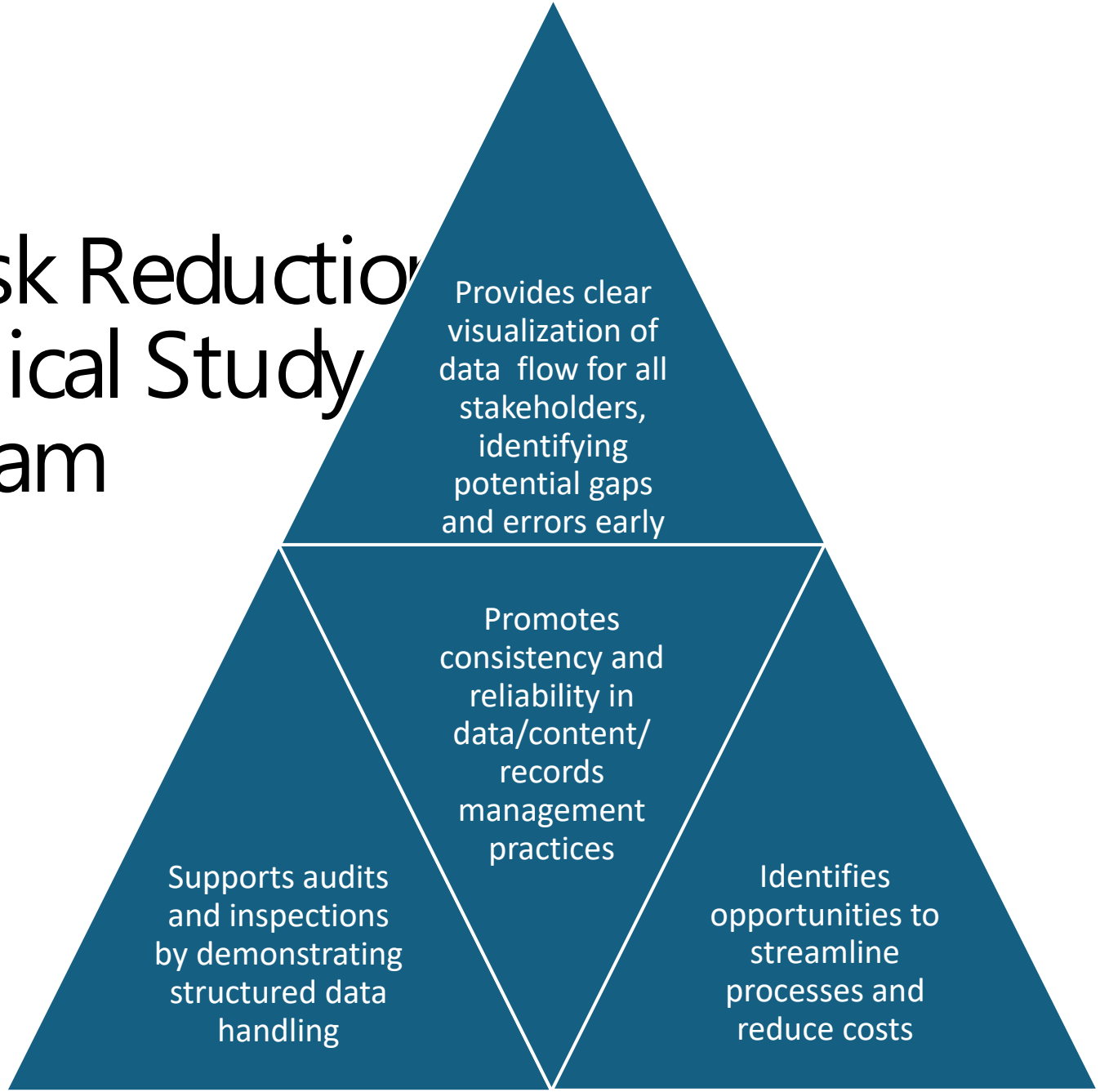
The Basics of Data and Records > Data Handling

ICH GCP R3 3.16

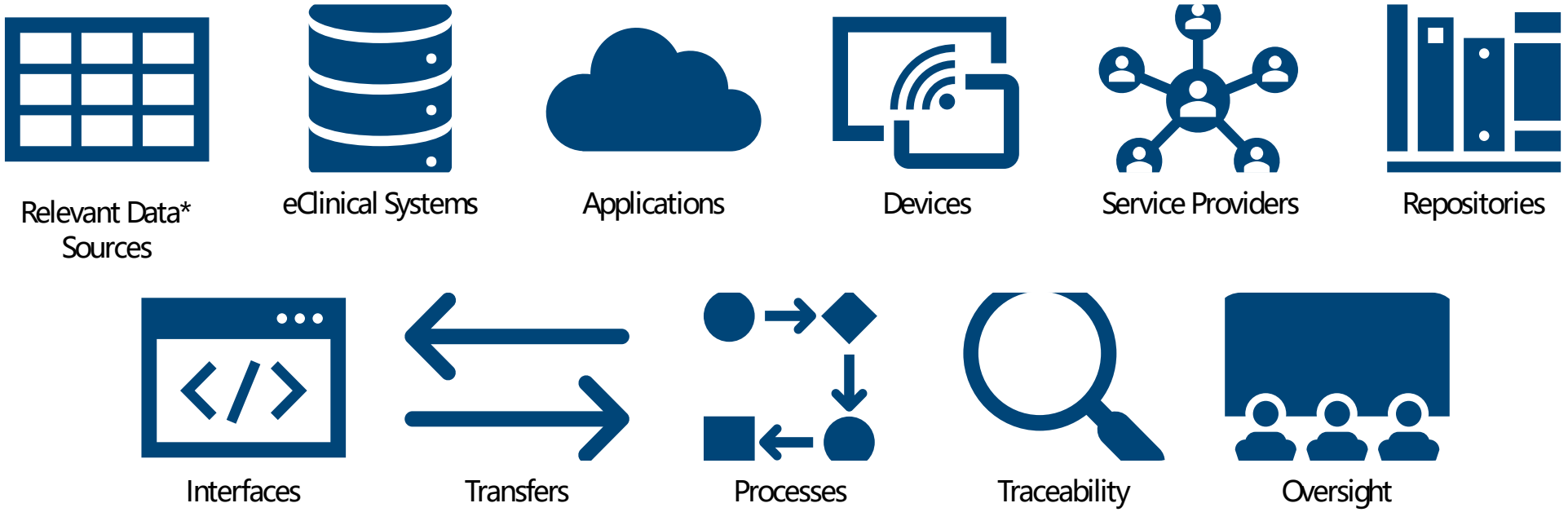



Clinical Study Data Flow Diagram
a visual tool used to map the movement of data within a clinical study
illustrates how information is collected, processed, reviewed, and archived
highlighting interactions between participants, clinical staff, electronic systems, and data management teams
ensures transparency, efficiency, regulatory compliance, and data integrity throughout the study lifecycle

Clinical Study Risk Reduction through the Clinical Study Data Flow Diagram



Components of a Study Clinical Data Flow Diagram



* **Data** — Clinical, operational, safety, and related study information

Documents — TMF records, reports, outputs, and supporting evidence

Metadata — Attributes that describe content, context, lineage, and ownership

Electronic content — Other digital outputs created or collected during the study

The Clinical Study Data Flow Diagram

TMF Standard Model V1 - *Draft* - Record Type

Zone #	Zone Name	Record Group	Record Type	Purpose/Description
12	eClinical	Data Oversight	Data Flow Diagram	To document the flow and lifecycle of study data from its generation or collection through processing, transfer, transformation, review, analysis, reporting, and retention, as applicable. The Study Data Flow Diagram identifies relevant data sources, systems, applications, devices, service providers, repositories, interfaces, transfers, and processing activities to demonstrate how study data move through the study data environment and support understanding, traceability, and oversight of the data lifecycle.

Data Flow Diagrams in Inspections

During inspections, there is an increasing expectation to be asked for a clear, study-level view of how data is generated, processed, managed, moved, and archived.

Clarity

Shows where study data and content originate, move, change hands, and land.

Traceability

Connects processes, systems, stakeholders, and controls across the trial lifecycle.

Readiness

Creates a common reference point for audit and inspection preparation and conduct.



Data Flow Diagrams Supporting Study Management

The diagram is not a one-time inspection artifact.

Embed	Incorporate the diagram into clinical study management processes.
Prepare	Use it to align study teams before audit or inspection activity.
Conduct	Reference it during inspection dialogue to explain where content comes from and how it is managed.
Improve	Capture lessons learned and refine the diagram as processes or systems evolve.



Stakeholder Alignment is the Real Value

A useful diagram turns a fragmented trial ecosystem into one shared picture.

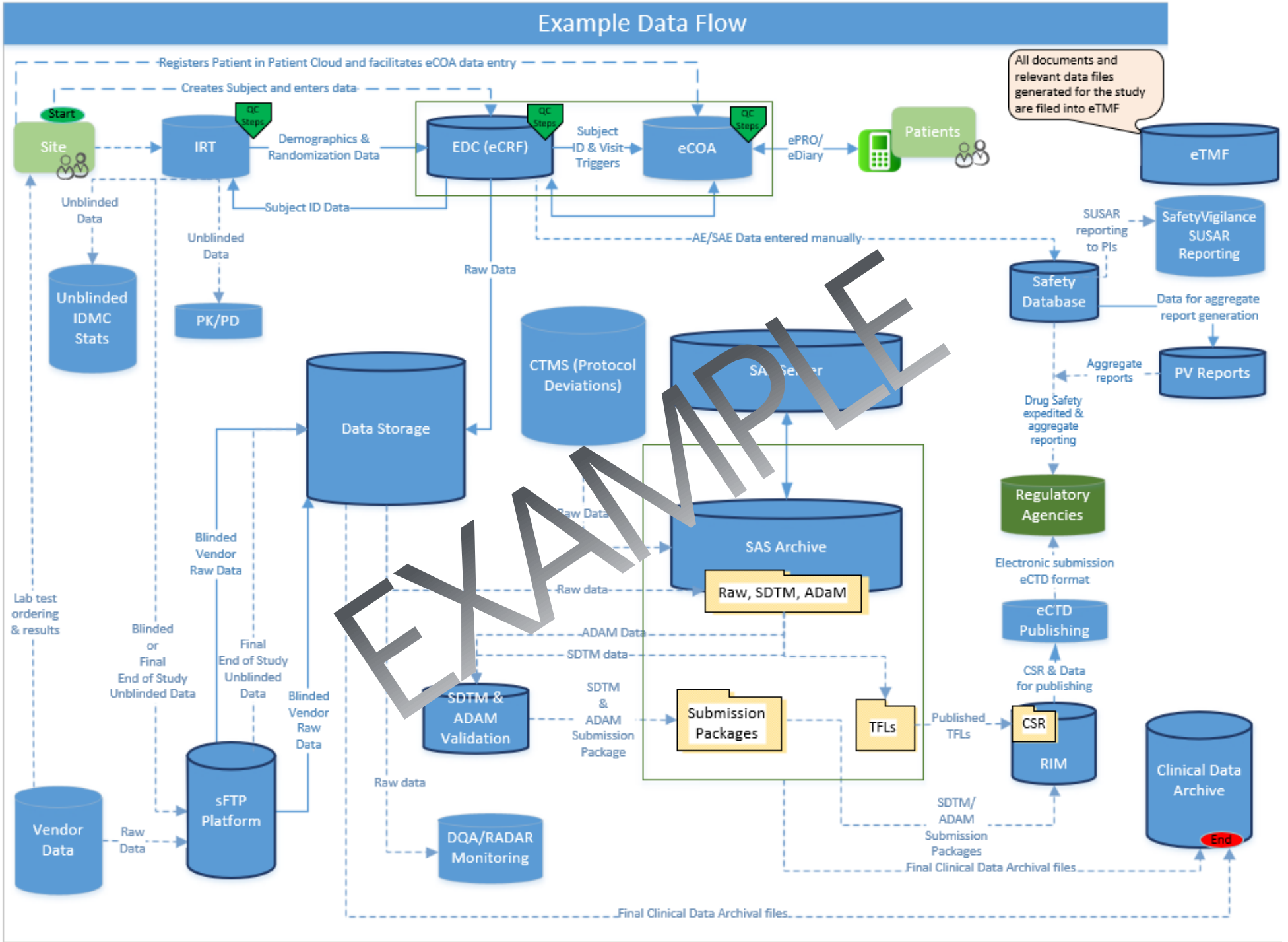
Sponsor / Study Team	Defines the study-specific view and uses it for oversight.
Clinical Operations and Data Functions	Explain how information is generated, transferred, and used.
Quality / Compliance / TMF / Regulatory	Use the diagram to prepare for, support, and respond during audits or inspections.
Service Providers / System Owners	Clarify handoffs, source locations, and operational dependencies.

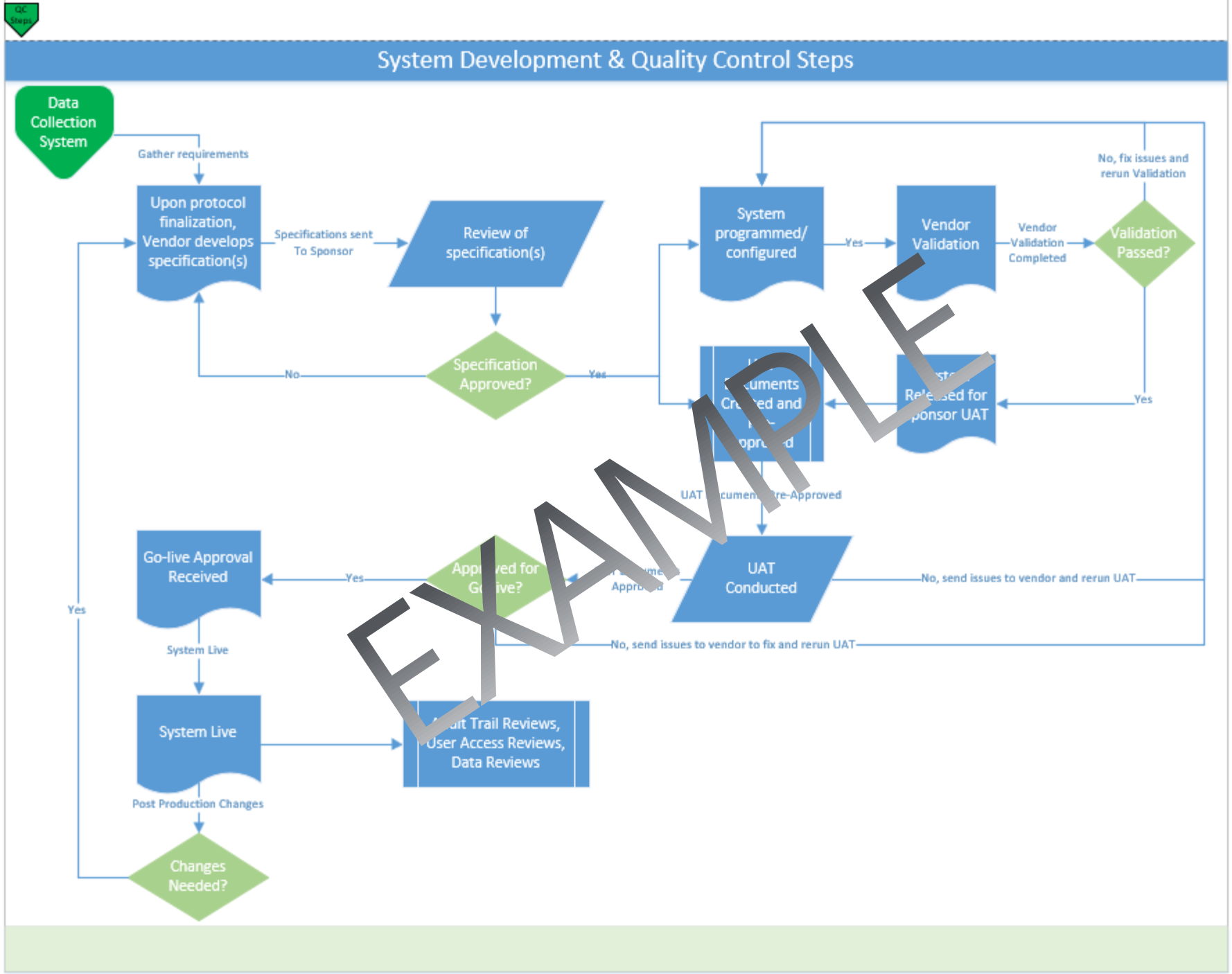


Sponsor case study

Real-world example of how Data Flow Diagrams were introduced at a sponsor company, and how use has evolved

Example Data Flow




QC Steps
System Development & Quality Control Steps
Data Collection System
Gather requirements
Upon protocol finalization, Vendor develops specification(s)
Specifications sent To Sponsor
Review of specification(s)
Specification Approved?
No
Yes
System programmed/ configured
Yes
Vendor Validation
Vendor Validation Completed
Validation Passed?
No, fix issues and rerun Validation
Yes
Released for Sponsor UAT
Documents Created and Approved
UAT Documents Pre-Approved
UAT Conducted
No, send issues to vendor and rerun UAT
No, send issues to vendor to fix and rerun UAT
Approved for Go-live?
Yes
Go-live Approval Received
System Live
System Live
Audit Trail Reviews, User Access Reviews, Data Reviews
Post Production Changes
Changes Needed?
Yes
EXAMPLE

From Inspection Response to Standard Practice

WHERE WE ARE NOW

Standard practice.

Not a response.

No longer an inspection deliverable — a planning step at study start.



THE DIAGRAM

Built for every study

All studies, not only those inspected

Created at study start

Scoped for data in submission packages



THE COMPANION DOCUMENT

The Data Flow Plan

A document to compliment the diagram

Describes each system and the data it holds

Blinded and unblinded data handling

cdisc®

Starting Early: Stakeholder Alignment in Practice

A study management tool we work from — not a retrospective narrative.

Sponsor and study team aligned

The whole team sees the flow early

Not only data-adjacent functions

Downstream functions informed

Recipients see how data reaches them

Context for what arrives, and when

Provider handoffs clarified

How and how often vendor data arrives

Dependencies and risks surfaced early

Thank You!



Questions?

