Data Flow Diagram Framework and Template

ICH E6(R3) – Good Clinical Practice

Version 1.0 dated 14 January 2025

ACRO

TransCelerate BIOPHARMA INC.

Disclaimer

- Any sample diagrams or data flow depictions contained herein are offered purely for illustrative purposes. The data flow and any data flow diagram will vary depending on the type of trial and circumstances of the particular trial being conducted.
- Any party using this Data Flow Diagram Framework & Template bears complete responsibility for making its own decisions as to what data flow methods and data flow diagram might work best for its particular circumstances.
- Neither TransCelerate BioPharma nor ACRO bear any responsibility or liability for any party's use or implementation of the content set forth herein.

Study Data Flow

ICH E6(R3): Section 3.16.1c Data and Records

The sponsor should pre-specify data to be collected and the method of its collection in the protocol (see Appendix B). Where necessary, additional details, including a data flow diagram, should be contained in a protocol-related document (e.g., a data management plan).

A clinical study data flow diagram is a visual representation of how data moves within a clinical trial, from its from its capture, review, finalization and archiving. It illustrates the flow of information between stakeholders, systems, and processes involved in the clinical study.

Why is it important?
A clinical study data flow diagram is essential for ensuring transparency, efficiency, compliance, reliability in clinical trial results and supporting protection of the patient's rights, safety and well-being.

Clarity and Communication: A data flow diagram provides a clear visualization of the entire data flow process. It helps stakeholders understand how data is captured, finalized and exchanged throughout the study lifecycle.

Risk Identification and Mitigation: By mapping out the data flow, potential gaps or errors in the data management process can be identified early on and corrected. This allows identification and implementation of appropriate risk mitigations to ensure data integrity, traceability and security.

Regulatory Compliance: A data flow diagram serves as a valuable tool for demonstrating compliance with evolving regulatory requirements and supporting the facilitation of audits or inspections.

Efficiency and Optimization: Understanding the data flow helps identify opportunities for streamlining processes and improving efficiency in data capture, review, and finalization. This can lead to cost savings and process optimization.

Quality Assurance: A well-designed data flow diagram promotes consistency and standardization in data management practices, enhancing the overall quality and reliability of study data.

Key components of study data flow diagrams

Data Capture/Collection*

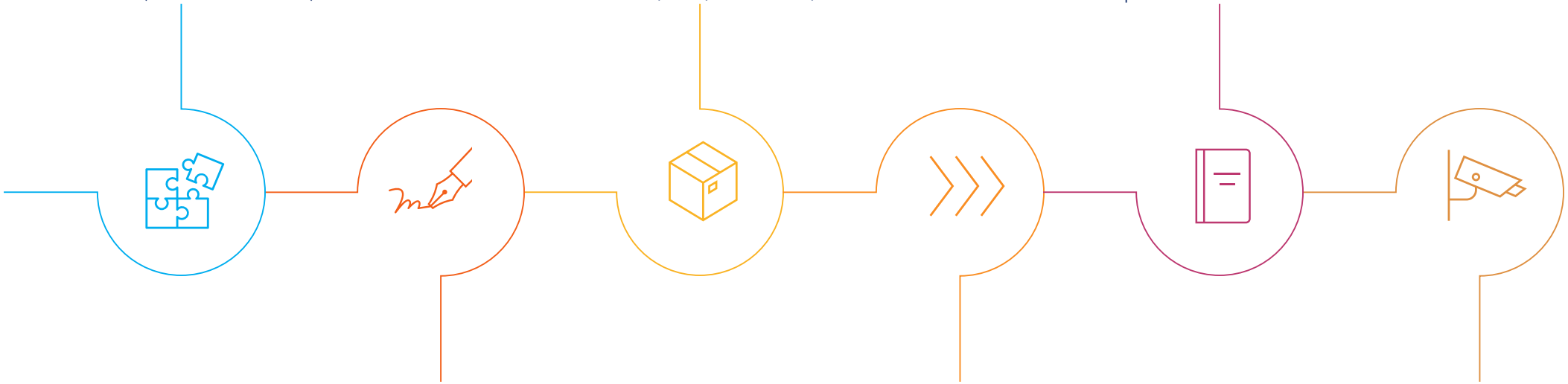
This includes the process of collecting various types of data from study participants, such as demographic information, medical history, laboratory results, and clinical assessments. Data collection methods may involve electronic data capture (EDC) systems, paper-based forms, wearable devices, or direct observation.

Data Storage*

Data collected and entered is stored in a secure database or repository. This may involve both local and centralized storage solutions, depending on the scale and complexity of the study.

Reporting and Dissemination*

Study results and findings are compiled into reports or publications for dissemination to stakeholders, including investigators, regulatory authorities, and the scientific community. This step may also involve the generation of data visualizations or summaries to facilitate understanding and interpretation.



Data Entry*

Once collected, data is entered into databases or systems for storage and management. This step involves data entry by investigational site personnel or study participant to ensure accuracy and completeness of the data.

Data Processing and Analysis*

Data undergoes various processing steps, including cleaning, coding, and transformation, before being analyzed. Statistical analysis is conducted to derive insights and conclusions from the data, which may involve the use of specialized software or algorithms.

Data Security and Compliance*

Throughout the data flow process, measures are implemented to assure the security, integrity, and confidentiality of the data. This includes compliance with regulatory requirements such as Good Clinical Practice (GCP) guidelines and data protection and privacy regulations.

* Data Verification will be performed at various stages in the process

ACRO

TransCelerate BIOPHARMA INC.

Introductory Notes

- The template on slides 6 to 10 is presented in PowerPoint format but can be transferred to another format (e.g., Visio)
- The data flow diagram can be created for an individual study or for a pool of studies if the data flow is the same
- The example diagram on slide 10 can be adapted as needed. For example:
  - It can include more or less data collection tools and/or processes
  - Arrow format can be adapted depending on the data flow model used for the study
- Data flow diagram to be version controlled and filed in Trial Master File

<Study or Pool of studies>

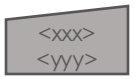
Data Flow Diagram

Version <xxx>

History of changes:

Version	Changes	Date
<Enter version number>	<Enter summary of changes and rationale>	<Enter date>

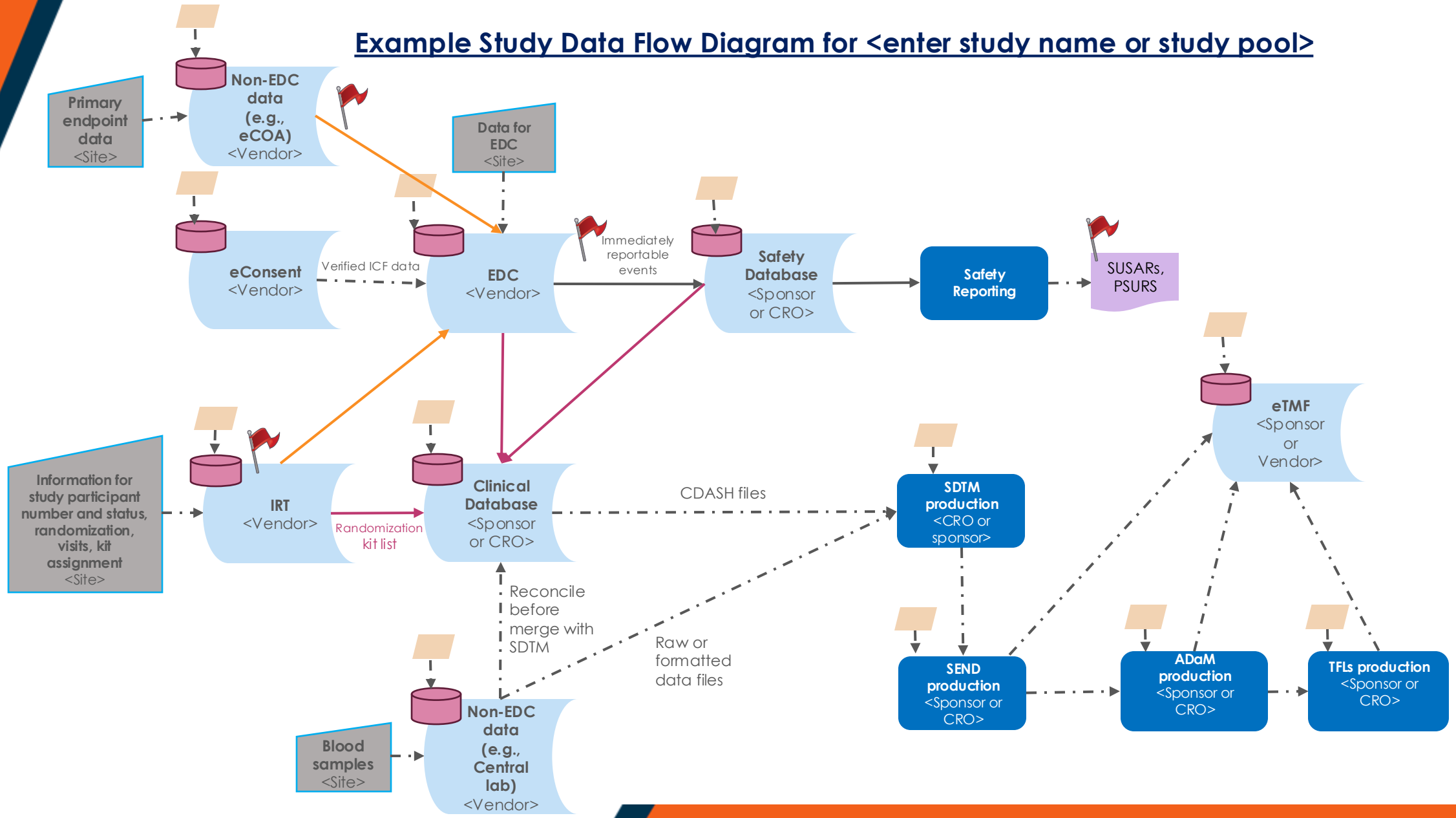
Legend

	Site or study participant data input, where <xxx> is the type of data (e.g.: EDC, lab sample, MRI, ECG, ePRO data, …) and <yyy> is the stakeholder producing the data (e.g.: study participant, site)
	Data Store, where <xxx> is
	Metadata
	Data process, where <xxx> is the name of the process (e.g.: Safety Reporting, SDTM Production,…) and <yyy> is the name of stakeholder (Sponsor, CRO, vendor)
	Indicates when data store is a file (to be added above a data store)
	Indicates when data store is a Database (to be added above a data store)
	Indicates critical data points or process(es) (to be added above a data input or a data flow, or a data store)
	Automated data flow (not requiring human intervention)
	Manual data flow (requiring human intervention)
	Electronic data transfer
	Data integration

List of Abbreviations

ADaM	Analysis Data Model
CDASH	Clinical Data Acquisition Standards Harmonization
CRO	Contract Research Organization
ECG	Electrocardiogram
ePRO	Electronic Patient-Reported Outcome
eTMF	Electronic Trial Master File
SDTM	Study Data Tabulation Model
SEND	Standard for Exchange of Nonclinical Data
TLF	Tables, Listings, and Figures

Example Study Data Flow Diagram for <enter study name or study pool>



NOTE: This diagram is an example that must be adapted based on the sponsor's processes and the study needs