# Data Governance Framework

## ICH E6(R3) – Good Clinical Practice

Version 1.0 dated 14 January 2025

ACRO

TransCelerate BIOPHARMA INC.

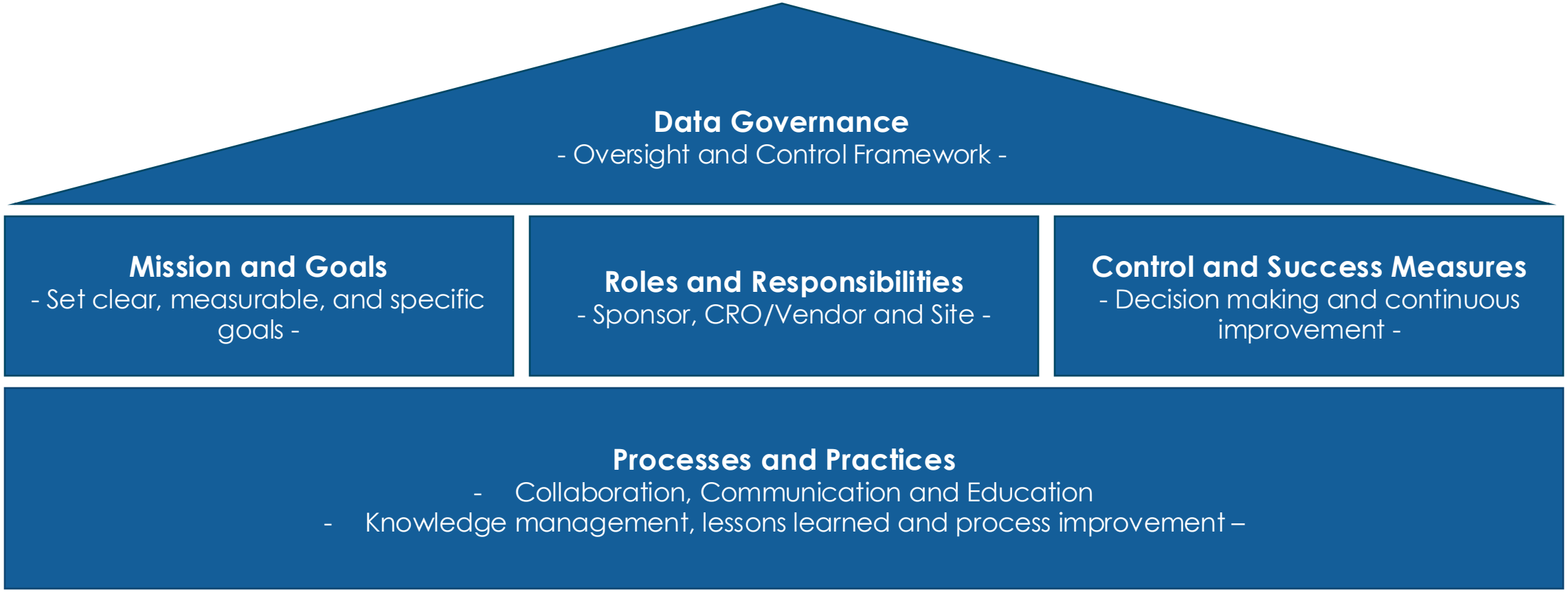
# Introduction

- **ICH E6(R3)** introduces **a new section on Data Governance (Section 4.0)** that incorporates the oversight and control of clinical trial-related information to ensure the identification, purpose, availability, usability, traceability, integrity, security, and quality of data throughout its lifecycle, irrespective of the format in which the data are collected or generated.
- This tool provides an overview of some of the constituent parts of a Data Governance framework along with controls and resources for Data Governance. It provides **TransCelerate-ACRO co-developed solutions** that provide some possible approaches for compliance with ICH E6(R3).
- Organizations are responsible for developing their own fit for purpose data governance that complies with relevant laws and regulations.

ACRO

TransCelerate BIOPHARMA INC.

# What is Data Governance?




ACRO

TransCelerate BIOPHARMA INC.

# Definition

- Data governance is the oversight and control of clinical trial-related information to ensure the **identification, purpose, availability, usability, traceability, integrity, security and quality of data throughout its lifecycle**, irrespective of the format in which they are collected or generated. Data Governance involves data identification, data ownership, and accountability, and linking data to critical to quality factors.
- Data governance also requires oversight and control mechanisms to ensure compliance with policies, standards, regulations, and best practices. An effective data governance strategy aims to establish **accountability, transparency, and consistency in data-related decision-making processes** across the organization. Data governance is essential for generating valid and reliable clinical trials results as well as ensuring the protection of participant safety, privacy, and rights.
- In "Guideline on computerised systems and electronic data in clinical trials" by the European Medicines Agency (EMA), data governance is explained as follows: "The **total of activities, processes, roles, policies, and standards** used to **manage and control the data** during the entire data lifecycle, while adhering to **ALCOA++ principles**" (see section 4.5.).

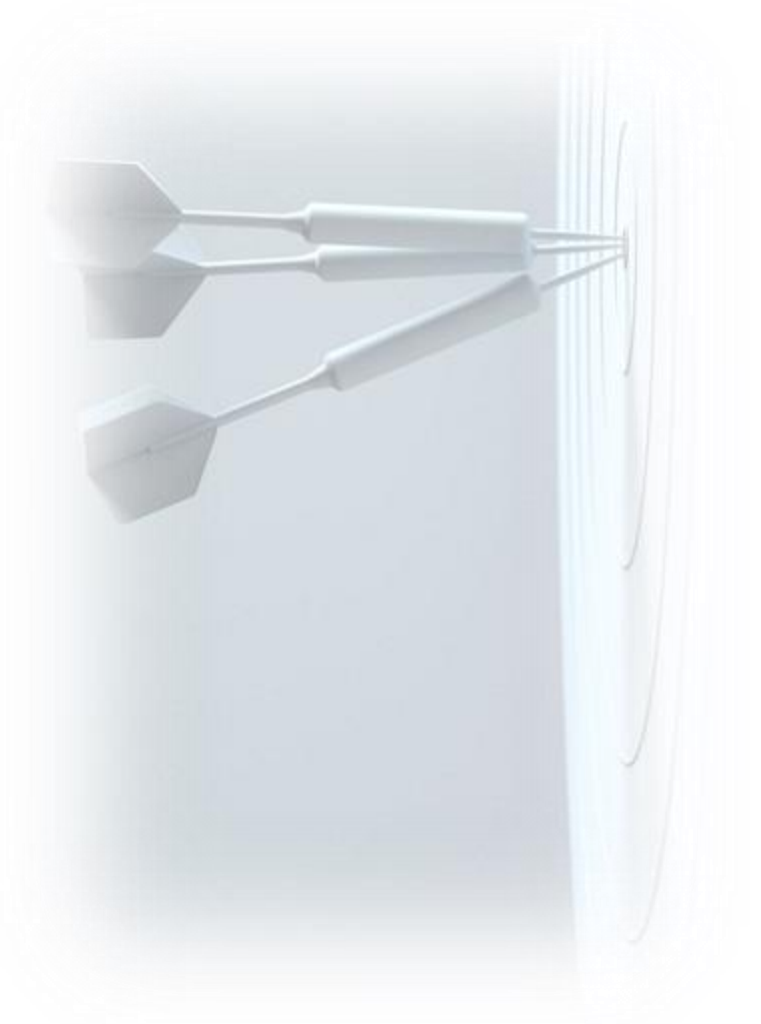
# Data Governance Mission and Goals

**MISSION**

Harnessing data governance as a catalyst for data-related decision making, driving continuous improvement, and delivering value to design, execution and management of clinical trial.

**GOALS**

- Establish accountability, transparency, and consistency in data-related decision-making processes across the organization
- Engage stakeholders in data governance activities
- Optimize processes and systems to leverage Data Governance oversight and controls
- Maximize the value of Data Governance with knowledge management, lessons learned and process improvement
- Understanding flow of data which come through multiple sources



ACRO

TransCelerate BIOPHARMA INC.

# Development of the Data Governance Mission Statement


- Provides direction and clarity in terms of processes and stakeholder involvement
- Can serve as evidence of a robust data governance process

- Cross-functional involvement of relevant parties
- Can be part of an enterprise risk assessment process
- Support from management

- Defines clear, measurable and specific goals
- Establishes objectives that are concrete and achievable
- Regularly reassess mission and goals, new emerging risks, and lessons learned

- When the data governance framework is introduced
- Have a plan in place for assessment of the mission and goals over time(e.g., new emerging risk, lessons learned)

ACRO TransCelerate BIOPHARMA INC.

# How Does Data Governance Support Clinical Trials?

Ensures generation of valid and reliable clinical trial data and results

Protects participant safety, privacy, and rights

Ensures appropriate oversight of data and metadata by responsible parties

Enables optimization of clinical trial execution

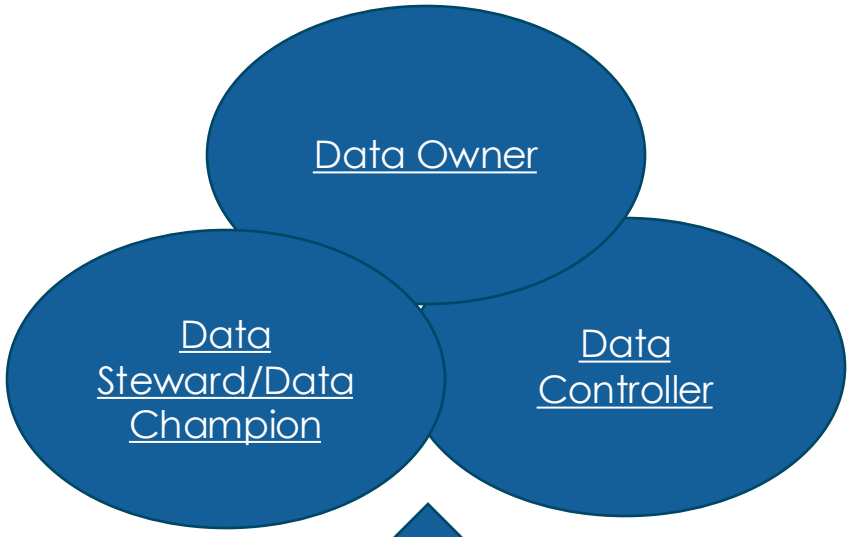
Enables the development of robust and sustainable data-driven decision-making processes

ACRO

TransCelerate BIOPHARMA INC.

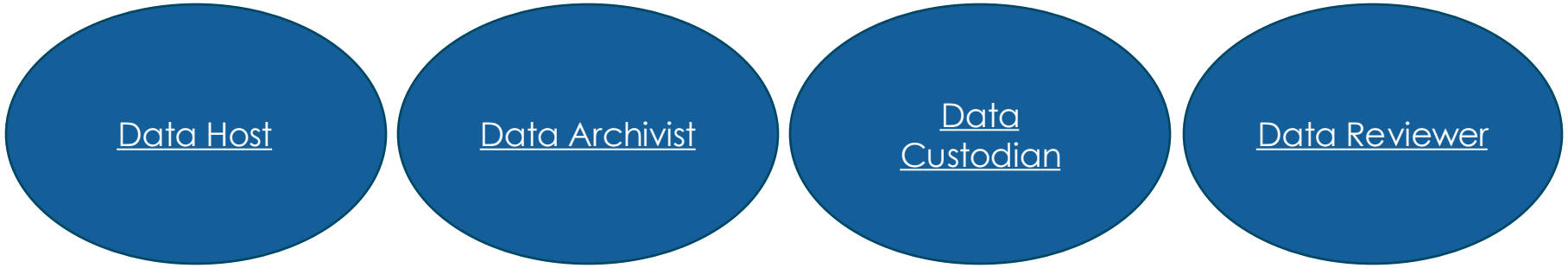
# Roles Involved with Data Governance

**Enterprise Level**




Interact with each other by oversight and control of Policies/Procedures and Operating Models

**Day-to-day operations at Study/Therapeutic Area Level**




ACRO

TransCelerate BIOPHARMA INC.

# Roles Involved in Data Governance

The roles listed below are examples of Data Governance roles. Depending on the organization, names of roles and responsibilities may differ.

- **PIC/S GMP Annex11:** Responsibilities for control of data can be allocated to a specific process owner. Companies should implement systems to ensure that responsibilities for systems and their data are appropriately allocated and responsibilities undertaken.
- **Data Owner:** Has the accountability of the data within a business process, which includes its metadata content and traceability across different systems
- **Data Steward/Data Champion:** Has a specialist role that utilizes an organization's data governance processes, policies, guidelines and responsibilities for administering an Organization's data in compliance with policy and/or regulatory obligations. The overall objective of a Data Steward is the data quality of the data assets, datasets, data records and data elements

# Roles Involved in Data Governance

- **Data Custodian:** Responsible for the safe custody, transport, storage of the data and implementation of business rules. Simply put, Data Stewards are responsible for what is stored in a data field, while data custodians are responsible for the technical environment and database structure.
- **Data Controller:** Oversees compliance with privacy and data protection regulations as applicable.
- **Data Reviewer:** Reviews identified critical data, considering business data review performed by business representative as well as technical/admin reviews that may be performed by IT reviewers, examples, QC reviewers, peer reviews, 4 eyes reviews, user access reviews, and audit trail review. The method of data review to be considered.
- **Data Archivist:** Assures controlled archiving of the data, metadata and access as directed through regulatory guidance, maintains tracking of all archived data from the date of the start of the archiving until the disposal of the data in compliance the required regulatory retention period and company standards.
- **Data Host:** Establishes a data platform wherein data are hosted, searched, and accessed.

ACRO TransCelerate BIOPHARMA INC.

# Sponsor, CRO, and Site Responsibilities

## Sponsor

- has responsibility and accountability to protect study participant's rights and safety, and to ensure study data integrity.
- is responsible to set up and share a RACI that outlines the responsibilities of each involved party
- is responsible to ensure that the CRO/Vendor is capable and qualified for the delivery of the services
- is responsible to ensure data transfer agreements and specifications are in place and aligned to ensure integrity in data flow with the different CRO/vendor involved in the study.

  In case of transfer of activity to CRO/Vendor, sponsor retains accountability for study data integrity and study participant's rights and safety.

## CRO/Vendor

- has a responsibility to protect study participant's rights and safety and to ensure data integrity and comply with regulations and sponsor agreement.
- must have a Data Governance framework in place.
- must have systems and controls in place to maintain data integrity of the study data.
- must follow the RACI that is established by the sponsor.
- must ensure appropriate and controlled direct access to data for the purpose of audits or inspections.
- data transfers must be executed as per Data Transfer Agreements.

## Investigator/Institution*

**For all systems and/or records**

- follow instructions for the use of the systems and production of trial records
- ensures staff is qualified and trained to use the systems
- has a responsibility to protect study participants rights and safety and to ensure data integrity.

**For systems and/or records contracted or developed by the Investigator/Institution to support the trial:**

- must have a Data Governance process in place for the systems they develop for clinical trial use.
- must have systems and controls in place to maintain data integrity of the study data.
- must follow the RACI that is established by the sponsor.
- must ensure appropriate and controlled direct access to data for the purpose of audits or inspections.

ACRO

TransCelerate BIOPHARMA INC.

** Systems and essential records that used specifically to support clinical trial execution*

# Processes and Practices

## Communication

**Cross-function and cross-country collaborations**

- Well planned communication strategy. There may be no one size fits all approach to communication since adapting to new technologies and systems is influenced by data literacy, each party's own policies/procedures and local practices/regulations.

**Education**

- Clear understanding of R&R involved in the activities, which is scope of data governance, regardless of where activities are conducted by which role.
- Continuing education and staying up to date with industry standard and evolving technologies.

## Continuous Improvements

**Knowledge management**

- A well-designed knowledge management framework helps the organization implement effective data governance, which can provide the best and optimized practices to meet compliance with GxP regulations.

**Lessons Learned**

- Agile and reflective practices become more important in a situation where data governance plays a critical role, such as in decentralized clinical trials, to take risk-proportionate approaches to known and emerging risks relating to data integrity.

ACRO

TransCelerate BIOPHARMA INC.

# Control and success measures

## Controls

**Sample proactive controls (Study Level):**

- Integration of Data Governance in Business Processes and procedural guidelines
- Study operational plans
- Training and education
- Vendor qualification and contracts/agreements on data governance
- Escalation and investigation processes of data governance issues
- Risk Identification and Review related to data quality

**Example monitoring of the controls (Enterprise Level):**

- Management Oversight on Data Governance (e.g. Data Governance Committee in place)
- Quality and Performance Indicators
- Audit and Inspection plans
- Assessment of the effectiveness of risk mitigations
- Vendor Quality Governance in place

## What success means?

- Reliability of clinical trial data and results
- Study participant's rights and safety are ensured
- Robust study documents (e.g. study protocol, operational plans)
- Successful clinical trial application and submission
- Smooth collaboration with different stakeholders
- Limited or absence of:
  - Data breach incidents/ Data Quality related incidents
  - Major and critical audits/inspections findings
  - Repetitive and systematic data governance issues
  - Process Deviations / Non-Compliance with the organization's standard

**Sample Measures:**

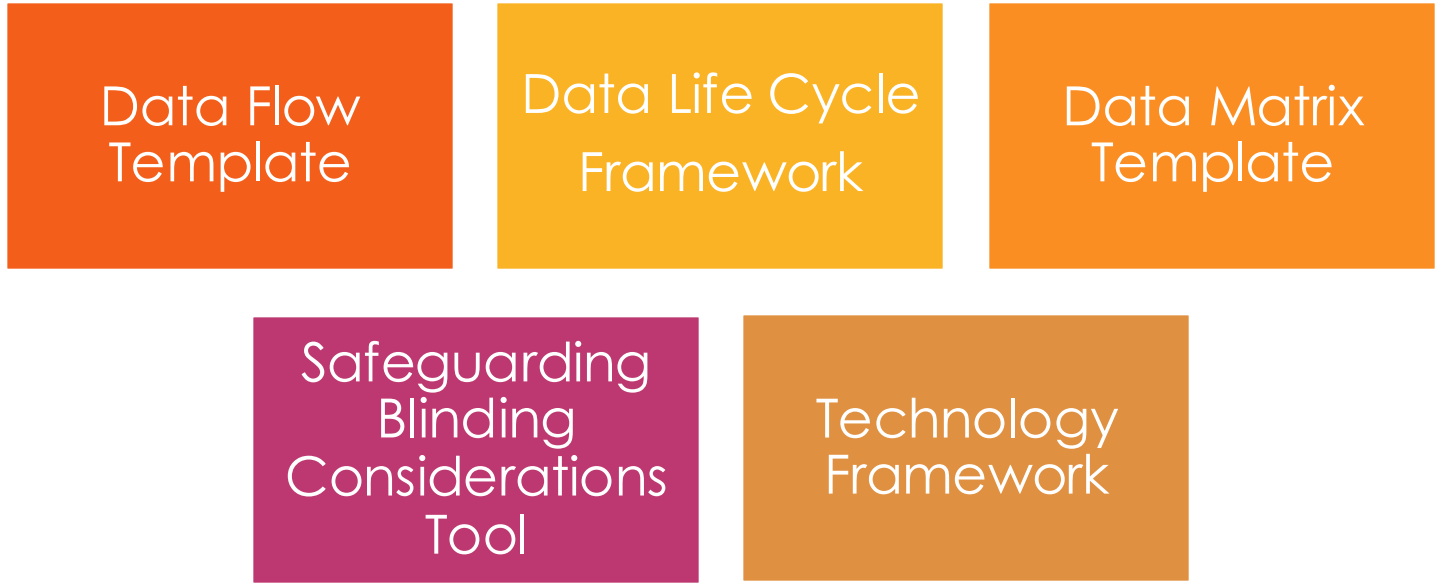
- Staff training
- Process Deviations / Non-Compliance with the organization's standard
- Access Management process to sensitive data
- Timely investigation of data governance issue
- Deviations from pre-defined Acceptable Ranges set for data quality and compliance of protocol/regulations/procedures
- Use and compliance to ALCOA++ principles

ACRO

TransCelerate BIOPHARMA INC.

# Co-Developed Solutions by TransCelerate & ACRO

- Data governance (DG) includes the **oversight and control** of clinical trial-related information to ensure the identification, purpose, availability, usability, traceability, integrity, security and **quality of data** throughout its lifecycle, irrespective of the format in which they are collected or generated. Data Governance involves data identification, data ownership, and accountability, and linking data to **critical to quality factors**.

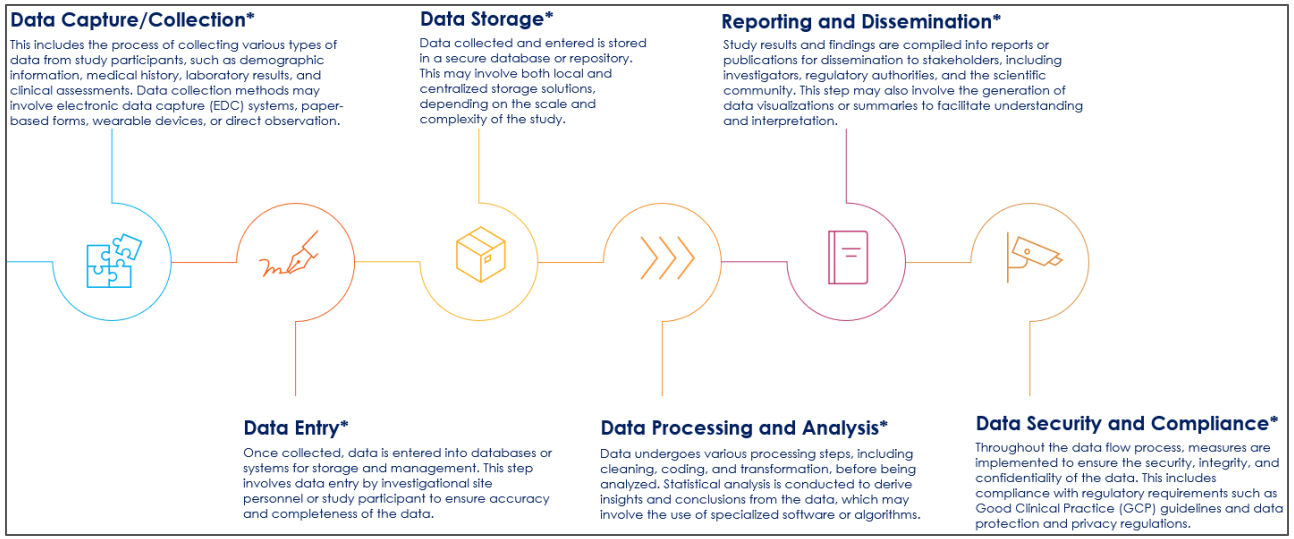



ACRO

TransCelerate BIOPHARMA INC.

# Data Flow Template

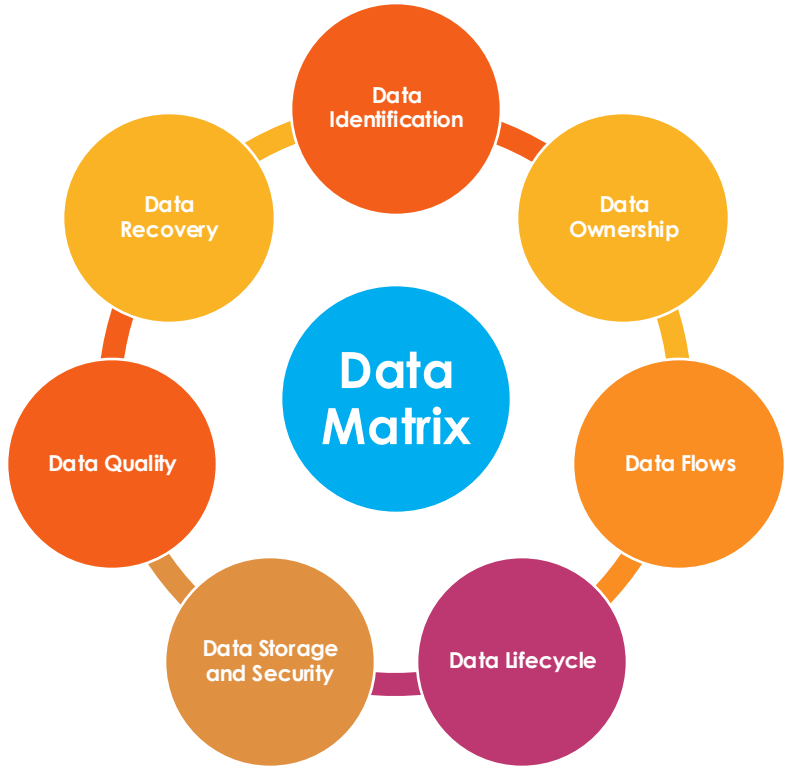
- **What is it?** A template to help companies map out relevant **data flows between various data collection tools** (e.g., EDC, ePRO, eCOA, Central labs) and involved parties (e.g., sponsor, CRO, third-party vendors) in a study.
- **Who is it for?** This template is intended for study sponsors, contract research organizations (CROs), and third-party vendors involved in clinical research.
- **How to use it?** This template can help **map out and visualize the interactions and data exchanges** between different data collection tools and stakeholders throughout the study process. This helps **increase clarity and coordination among all parties involved**.




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

# Data Matrix Template

- **What is it?** A template that can help companies outline their study data provenance and collection methods, data transformation, review techniques and frequency (including references to functional plans where reviews are fully described), and data analysis (TLFs and ADaMs). The data matrix is linked to highlight critical-to-quality (CtQ) data and processes.
- **Who is it for?** This template is intended for clinical research professionals, including study sponsors, contract research organizations (CROs), and other stakeholders involved in the collection, cleaning, assembly, and analysis of clinical study data.
- **How to use it?** This template can help users understand how data are collected, cleaned, assembled, and analyzed in a clinical study. It helps facilitate the application of ICH E6(R3) requirements for data governance by providing a clear and structured approach to managing study data. The template also includes links to the data matrix to identify CtQ data and processes, helping all involved parties have a clear understanding of the data management workflow.




ACRO

TransCelerate BIOPHARMA INC.

# Data Lifecycle Framework

- **What is it?** A slide deck that explains some of the **elements of the data lifecycle** (e.g., data capture, relevant metadata, data review, data corrections, data transfer, and finalization of data sets before analysis).
- **Who is it for?** This slide deck is designed for **clinical research professionals**, including study sponsors, contract research organizations (CROs), and other stakeholders involved in managing and analyzing clinical data.
- **How to use it?** Use this slide deck to **understand and clarify data lifecycle elements**. Click on the sections of interest to access detailed information about roles, responsibilities, definitions, and examples. This resource helps ensure everyone involved has a clear understanding of the data management process and their specific duties.

# Safeguarding Blinding

- **What is it?** Infographics that explain the **concept of safeguarding unblinding in clinical research**. They cover topics such as what blinded data is, why data is blinded, the importance of maintaining blinding, who may be unblinded, and the steps to take in case of unblinding.
- **Who is it for?** These resources are designed for **clinical research professionals**, including study sponsors, contract research organizations (CROs), and other stakeholders involved in managing and analyzing clinical trial data.
- **How to use it?** These infographics can facilitate **understanding the risks associated with data unblinding**. They provide practical examples and key points to consider, helping industry professionals maintain data integrity and comply with best practices in data management.

# Technology Framework

- **What is it?** A PowerPoint slide deck that explains the **Computerized Systems (CS) requirements** outlined in ICH E6 R3. It covers procedures for using CS, training, security, validation, periodic reviews, system failure, technical support, and user management. It also includes TransCelerate and ACRO's proposed definitions and details the roles and responsibilities of those involved in the process.
- **Who is it for?** This slide deck is intended for clinical research professionals, including study sponsors, contract research organizations (CROs), and other stakeholders involved in the implementation and management of computerized systems in clinical trials.
- **How to use it?** Use this slide deck to clarify the CS requirements of ICH E6(R3) and understand the roles and responsibilities of those involved. Click on the sections of interest to access detailed information about roles, responsibilities, definitions, and examples. The tool also points to other relevant ICH guidelines, providing a comprehensive resource for managing computerized systems in clinical research.