iMATCH Data Hub Governance Framework

Contents

- Data Governance principles and regulations
- iMATCH Data Hub: Aligning data governance principles to a variable infrastructure
- Data Governance Implementation
- iMATCH Data Hub Tool Kits
- Governance Process Maps
- Activity Diagrams
- Framework Delivery Metrics

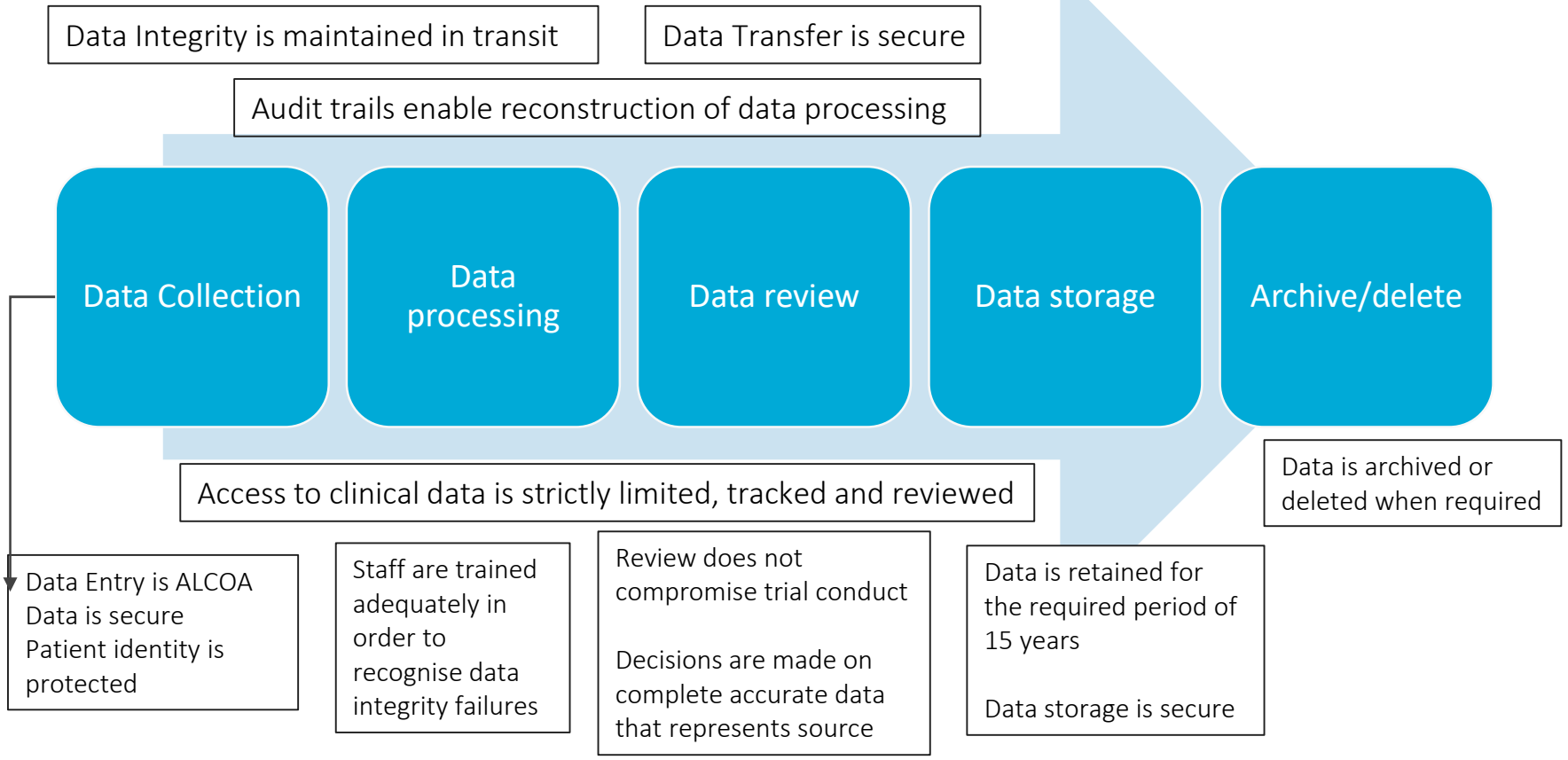
Governance Principles and Regulations

Data Governance is a regulatory requirement

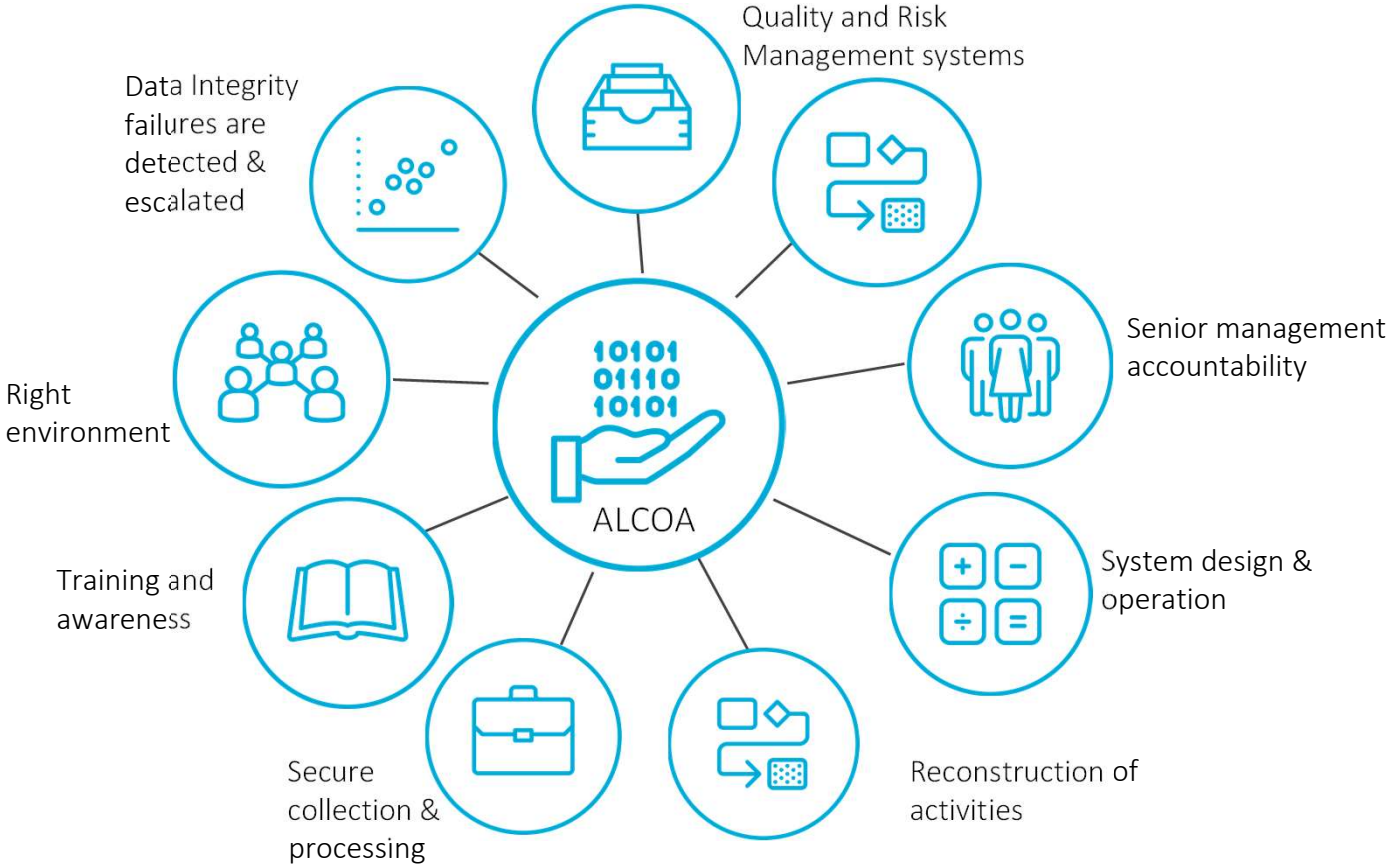
- Data Governance are the arrangements to ensure that data, irrespective of the format in which they are generated, are recorded, processed, retained and used in a way that maintains its integrity, quality and security throughout its lifecycle
  - Having confidence in the quality and the integrity of the data, minimises risks to patient safety and quality

- Data Integrity (the degree to which data are complete, consistent, accurate, trustworthy, reliable is a key aspect of data governance
  - There must be a strategy that is aligned to maintaining data integrity during any clinical data processing operation

Governance must cover all parts of the data lifecycle



Data Governance Components

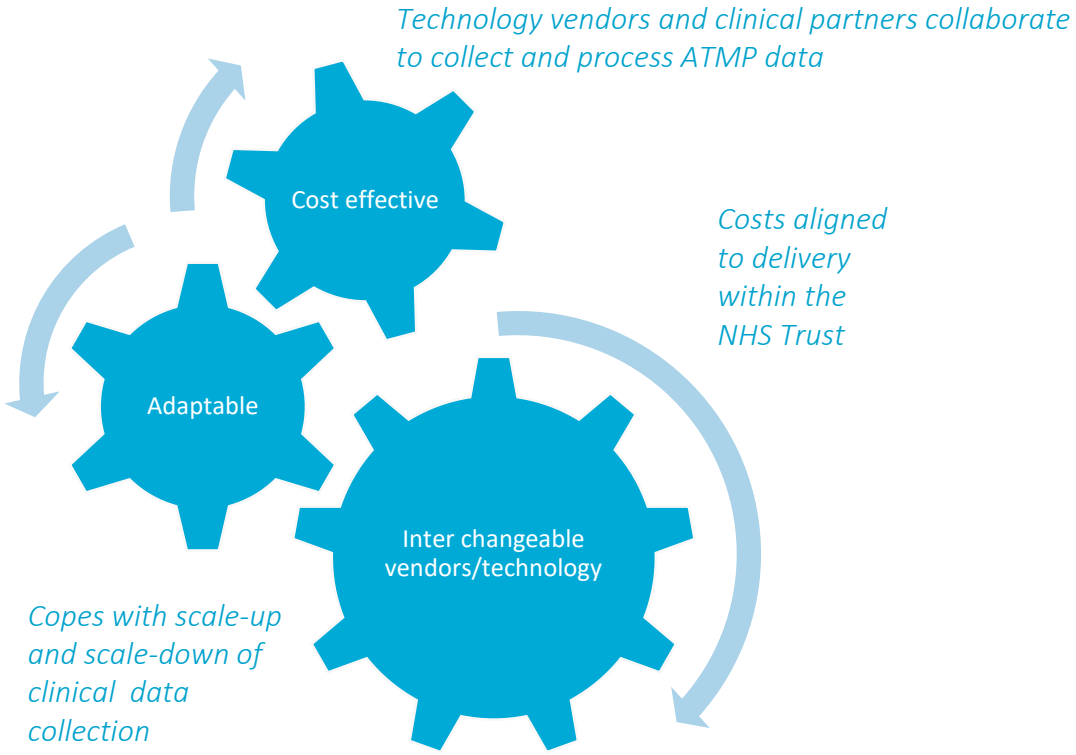


iMATCH Data Hub

Aligning Data Governance Principles to a Variable Infrastructure

iMATCH Data Hub

Designed for efficient and compliant processing of data from ATMP Clinical Trials or Therapy



Governance Challenges

- Vendors in the Data Hub are changeable
  - Some may be used routinely, others infrequently
  - Vendor selection will be determined by cost model and sponsor requirements.

- The sponsor is responsible for determining the trial design including how the data is processed.

- The iMATCH data hub governance framework will provide all the necessary elements for the system to operate compliantly and but it is up to the Sponsor to choose to implement it.

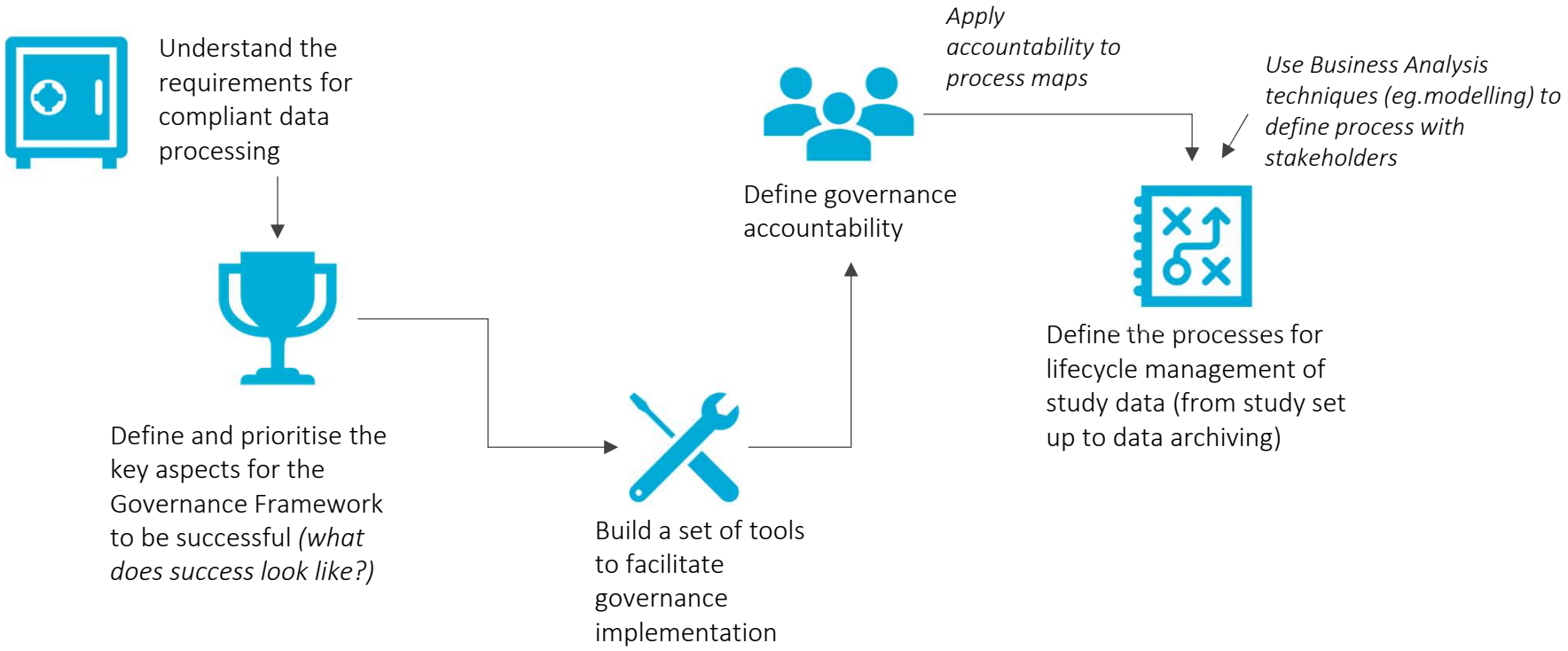
- Due to the variable nature of the Data Hub infrastructure
  - Data Governance will be vendor agnostic
  - It will focus on essential procedures, training and tool kits that enable compliant and efficient data processing

Data Governance Implementation

iMATCH Data Governance Objectives

- Will meet regulatory expectations ; MHRA, EMA, FDA
  - And will provide a structure to drive consistency and compliance for each study
  - The culture and understanding of the importance of data integrity and security are embedded
- Clear and transparent approach
  - Avoiding complexity
  - Straightforward for any vendor, auditor or regulator to navigate
  - Well-defined accountability for all stakeholders
- Adaptable and reusable
  - Consistent approach that is vendor agnostic
  - Can adapt to new regulations, new vendors, different types of trials

Process for Implementation



Data Governance Building Blocks

Define and prioritise the key aspects

Training, awareness and culture

- Employees at all levels will understand the importance of data integrity and the influence that they can have on the data
- Standard definitions and terms will be referenced from regulations

Quality Management System

- A documented system that provides an acceptable state of control based on the data integrity risk
- To control intentional and unintentional changes to data
- To ensure consistency in data processing operations
- Risk management approach

Ownership and Accountability

- Clarity on the roles that responsible organisations play in data governance
- Contracts and study specifications will clearly define roles and responsibilities
- Clear separation between system admins and data processers/reviewers

System design, operation and maintenance

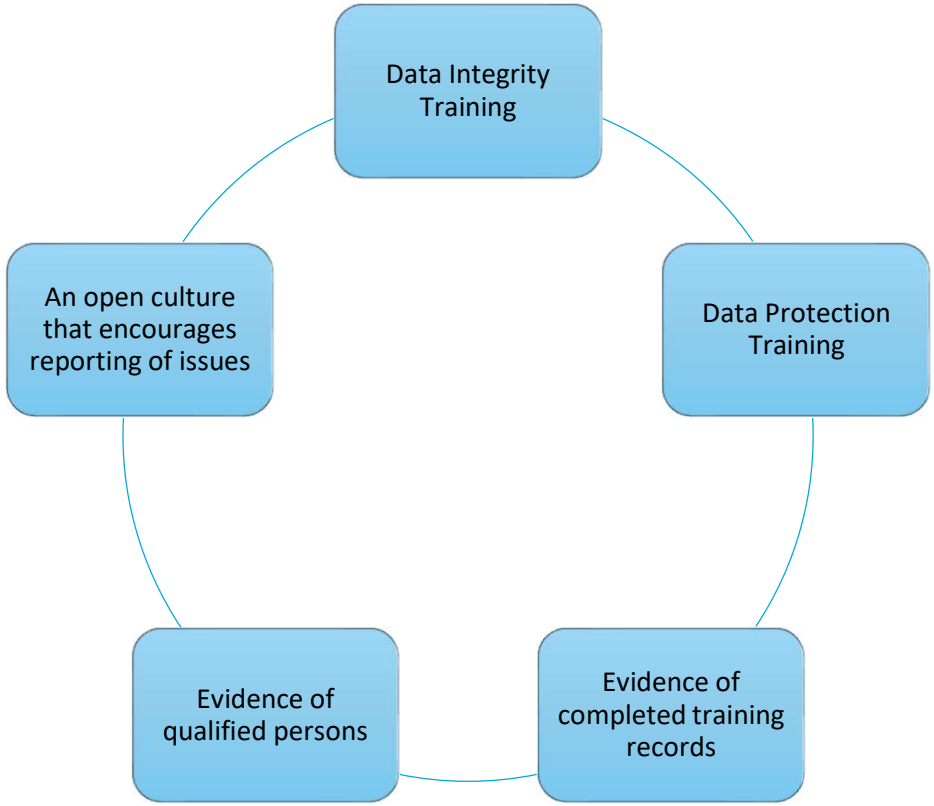
- Evidence of validated state of a process or a computerized system (ensuring accuracy of generated or recorded data)
- System Design approach should aim to minimise risks to data integrity and data protection
- Effective management of critical authorizations (protection of data to avoid integrity breaches during operation)

Training, Awareness, Culture

- Employees at all levels should understand the importance of data integrity and the influence that they can have on the data
- Training and awareness should emphasise the responsibility of employees to recognise and report data integrity failures

Vendors must demonstrate that data integrity principles and knowledge are embedded into their organisation

This can be achieved through regular training on Data Integrity -The GAP assessment tool will seek to obtain evidence of a vendors approach to Training and awareness

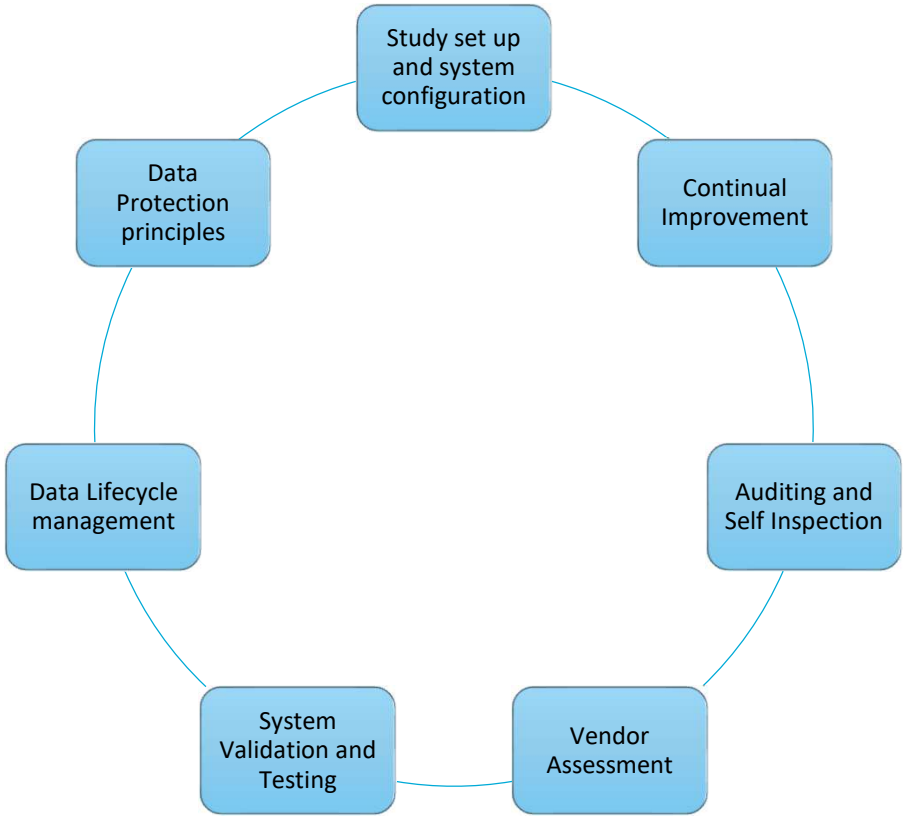


Quality Management

- A documented system that provides an acceptable state of control based on the data integrity risk
- A set of SOPs, WI's and Templates
  - To control intentional and unintentional changes to data
  - To ensure consistency in data processing operations

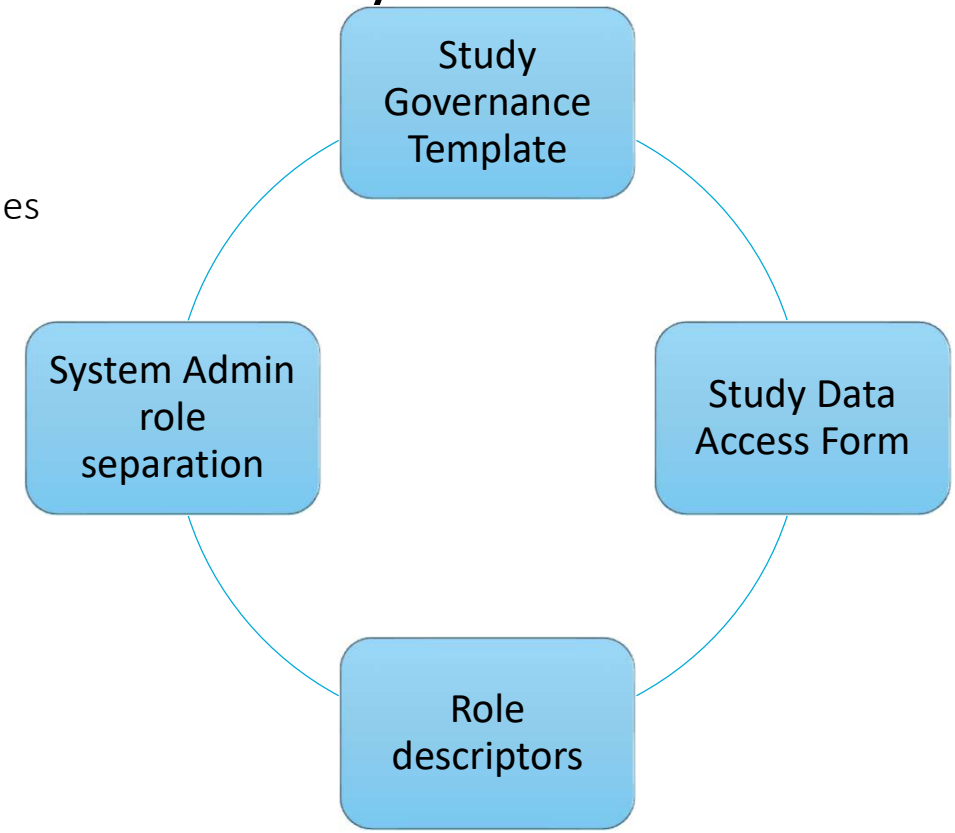
Tool Kit

The Data Hub Governance Framework includes a GAP assessment template to facilitate review of a vendors QMS to ensure it meets regulatory requirements and Data Hub standards



Ownership and Accountability

- Clarity on the roles that responsible organisations play in data governance
- Signatures against roles and responsibilities
- Clinical data access gatekeeping



Tool Kit

Reference document to guide appropriate role descriptors/separation

Study governance template for informal contract between technology vendors and sponsor to consider the appropriate configuration according to study design

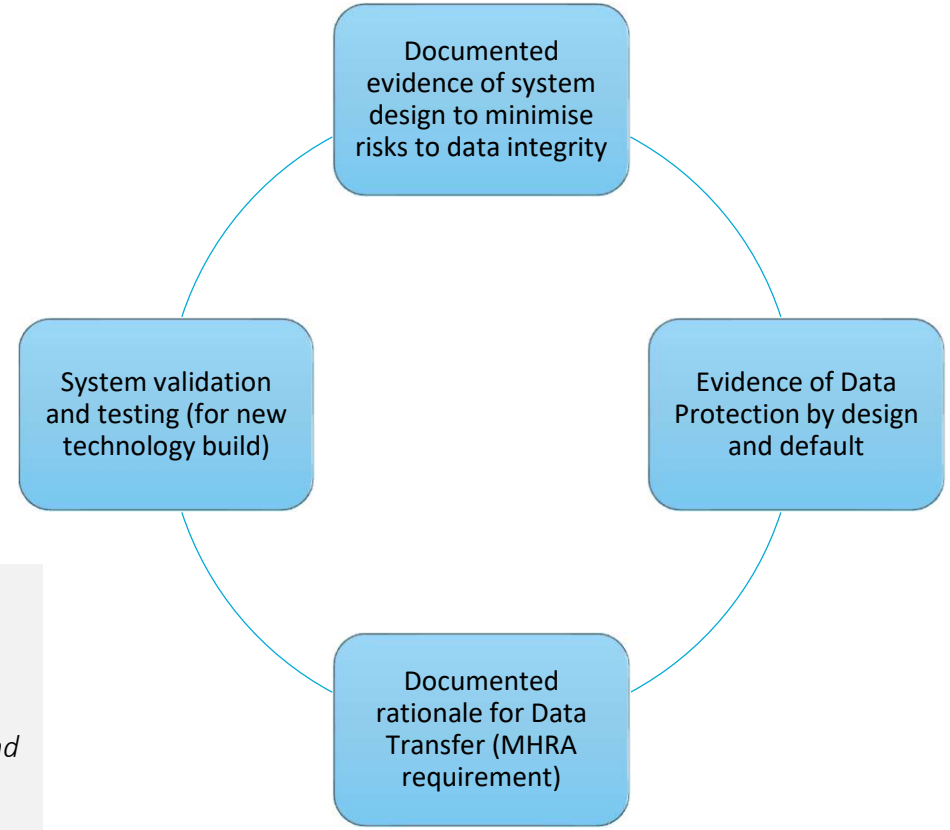
Study data access form

System design, operation and maintenance

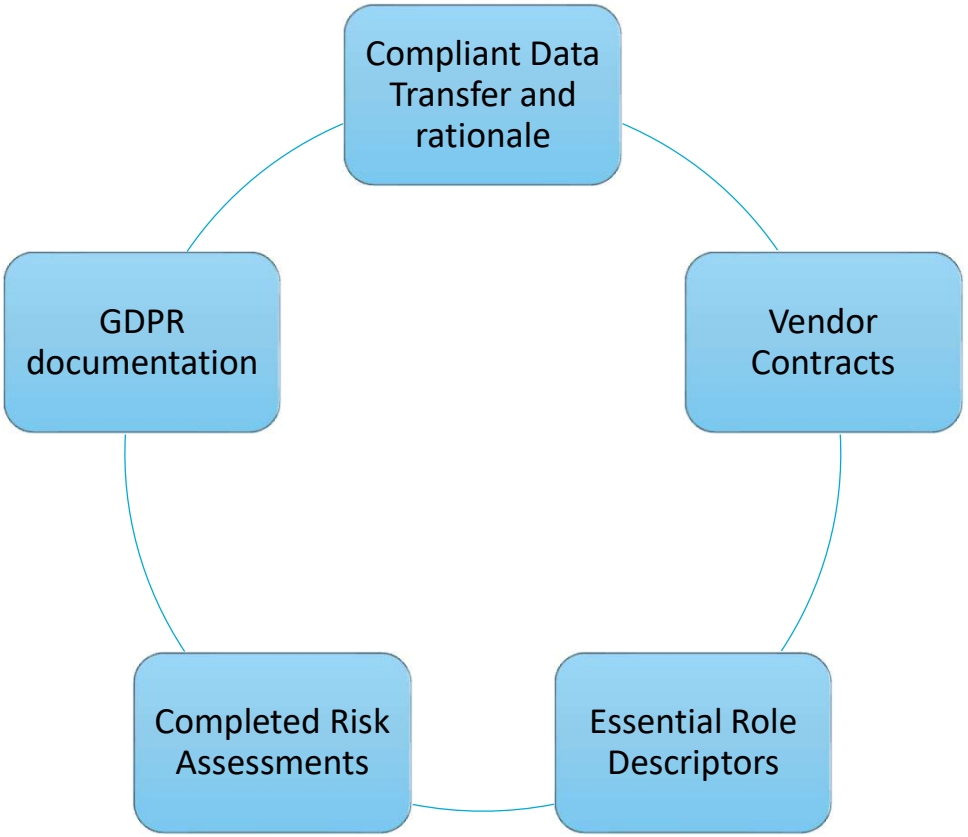
- System Design approach should aim to minimise risks to data integrity and data protection (especially relevant for risks associated with data transfer)
- Evidence of validated state of a process or a computerized system (ensuring accuracy of generated or recorded data)
- Effective management of critical authorizations (protection of data to avoid integrity breaches during operation).

Clear set of documentation to demonstrate DI considerations into system design and maintenance

Evidence of a risk-based approach for design and validation

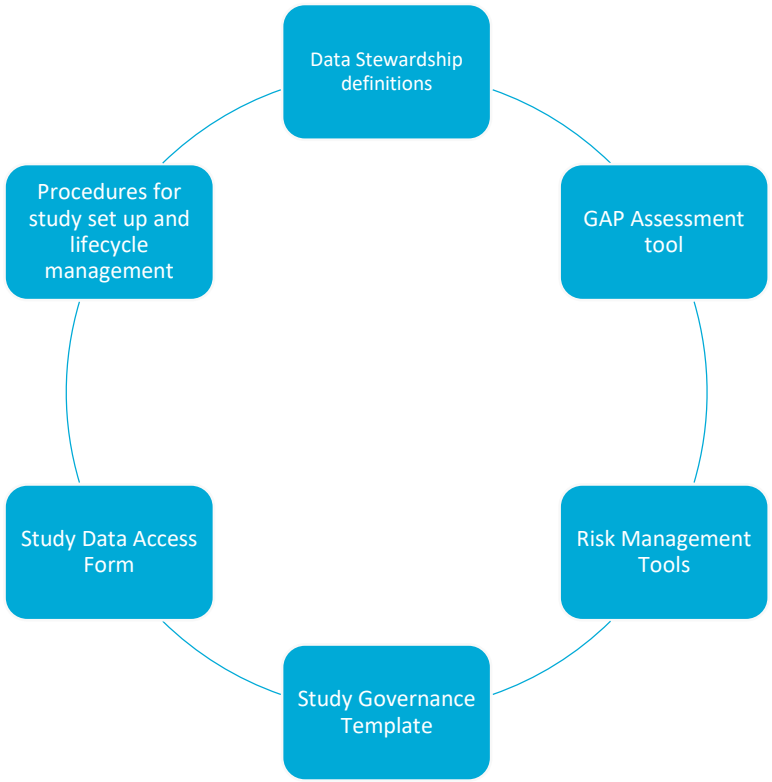


Additional compliance requirements



iMATCH Data Hub Tool Kits

Governance Tool Kit



Study Governance Template

- A document that forms an informal contract between the sponsor organisation and key stakeholders (including external vendors) to ensure system configuration , access and permissions and data review are all appropriate for the chosen study
    - Driven by the Sponsor or CRO
- It ensures that study set up for data processing using the technology components of the data hub result in no risk to study conduct from inappropriate access
- It defines roles and responsibilities between the sponsor organisation and data hub vendors involved in data processing to assign accountability
- It is a living document with version control that keeps track of any changes to requirements or study team/personal during the study lifecycle . This should be incorporated into any Data Management plan for the CRO or sponsor organisation.
- It requires review and signature from senior members of the Clinical study team including;
    - Sponsor Clinical Lead
    - Data Management Lead
    - Statistical Lead
    - Technology Vendor CEO

Roles and Responsibilities

Trial Sponsor

- Ensure data collection is aligned to trial objective
- Monitor patient safety
- Risk assess
- Ensure data quality and integrity
- Ensure the principles of data protection design and default are applied
- Ensure source data is stored/archived

CRO

- May assume operational responsibility for trial
- Data Management/Access
- Vendor assessment and selection
- Quality oversight
- Analysis and reporting
- TMF management

(Sponsor still accountable for safety and data protection)

Technology Vendors

- Implement technical and organisational measures to secure data
- Test and validate system
- Ensure secure storage and back up of data
- Meet regulatory standards
- Work with clients to fulfil compliance objectives (risk assessments etc…)

Defining Accountability

The Study Requirements Specification (SRS) forms an informal contract between key persons accountable for compliant data processing. It documents who is responsible for system configuration including access and permissions

Trial Sponsor

- Clinical Lead (CL)
- Data Protection Officer (DPO)

- ***CL:*** *To ensure that the study design and requirements for processing and analysis are clearly communicated and documented*
- ***DPO:*** *To facilitate the necessary compliance obligations for lawful processing of data including data hub risk assessment*

CRO

- Quality Compliance Lead (QCL)
- Data Management Lead (DML)
- Statistical Lead (SL)

- ***QCL:*** *To ensure that a comprehensive QMS is in place and quality oversight is managed effectively in the trial lifecycle.*
- ***DML:*** *To manage access and permissions to trial data*
- ***SL:*** *To ensure that use of systems and tools does not present a risk to study conduct*

Technology Vendors

- Vendor CEO

- ***Vendor CEO:*** *To engage with Sponsor and/or CEO to satisfy compliance requirements*
- *To endeavour to implement technical and organisational measures to reduce risk*

Other important role descriptors

- Demonstrate that the potential for committing Fraud is limited and could be detected
- Demonstrate that study conduct is not put at risk due to confusion around clinical data access

System Administrators

Data Management/Reviewers

Clear separation between system admins and those involved in the study data management/review.

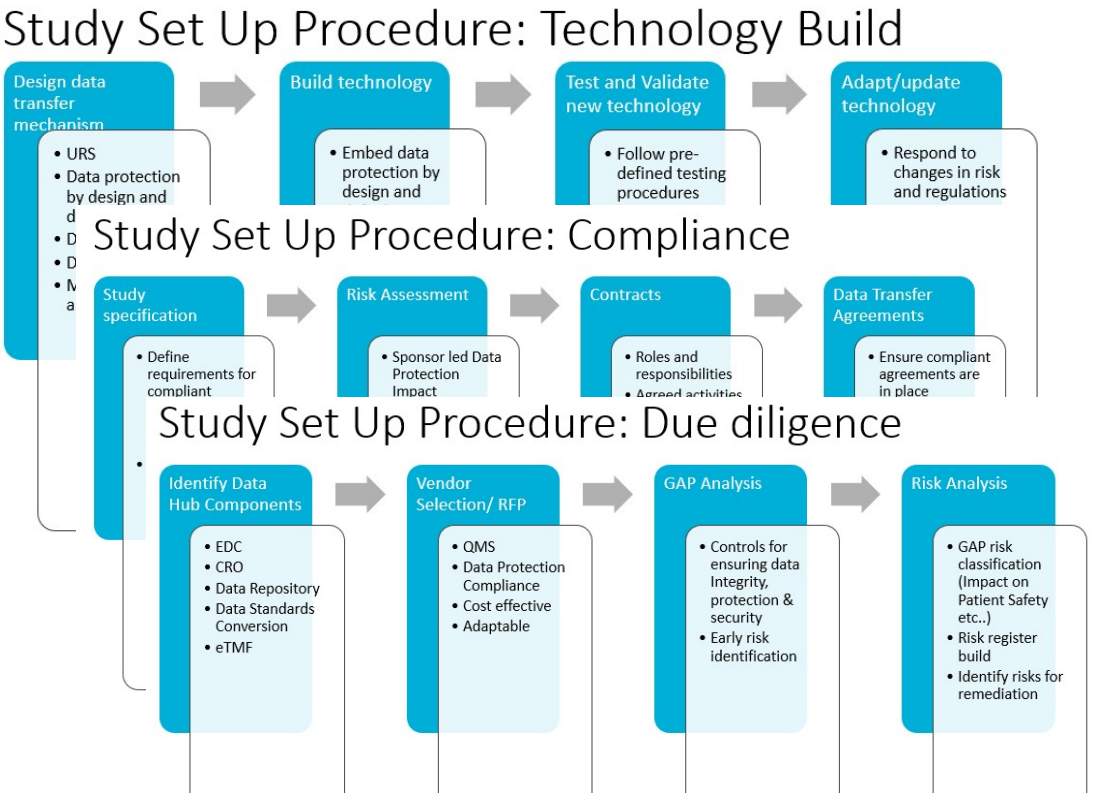
System admin removed from study design/objective and can apply an unbiased and regulated approach for managing access and authorisations to data

Governance Process Maps

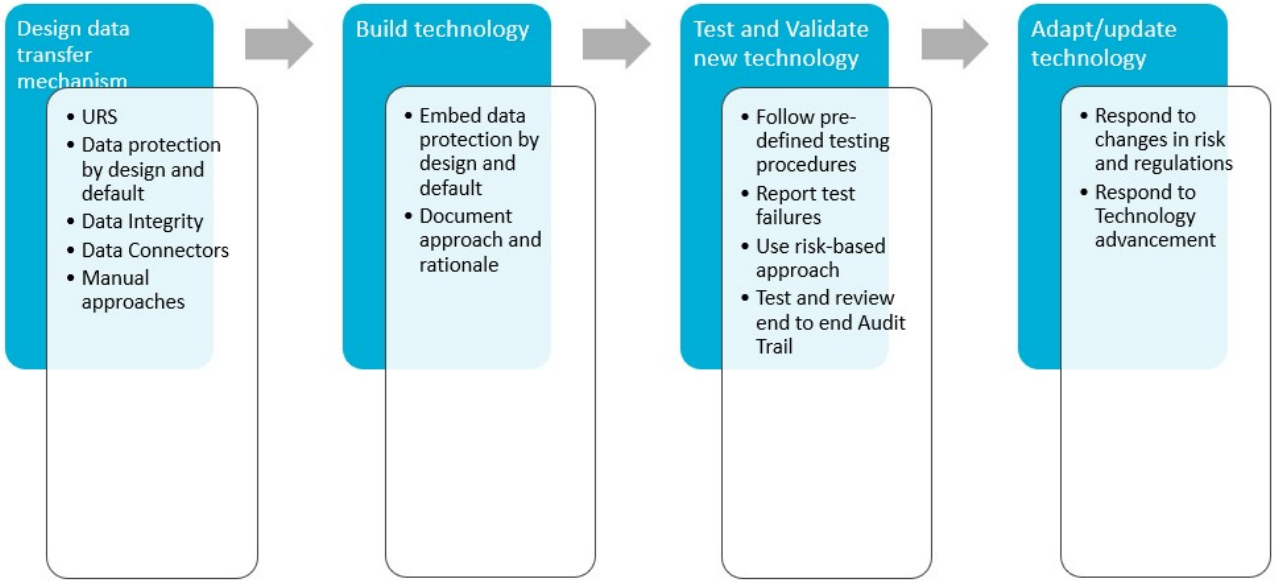
To guide compliance and consistency in study set up and data lifecycle

Defined processes and procedures

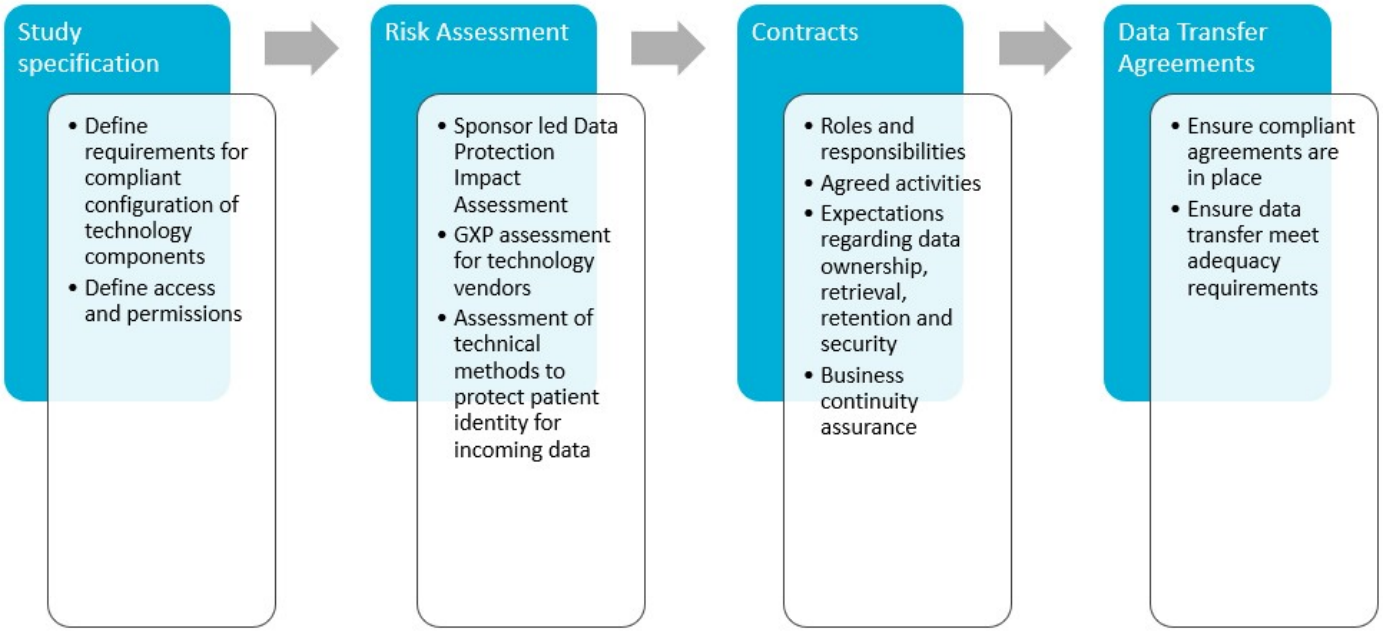
- A defined set of procedures to drive consistency and quality in configuration and set up
- Reduces data integrity issues
- Ensures all necessary steps are followed to comply with regulatory guidance and industry best practice



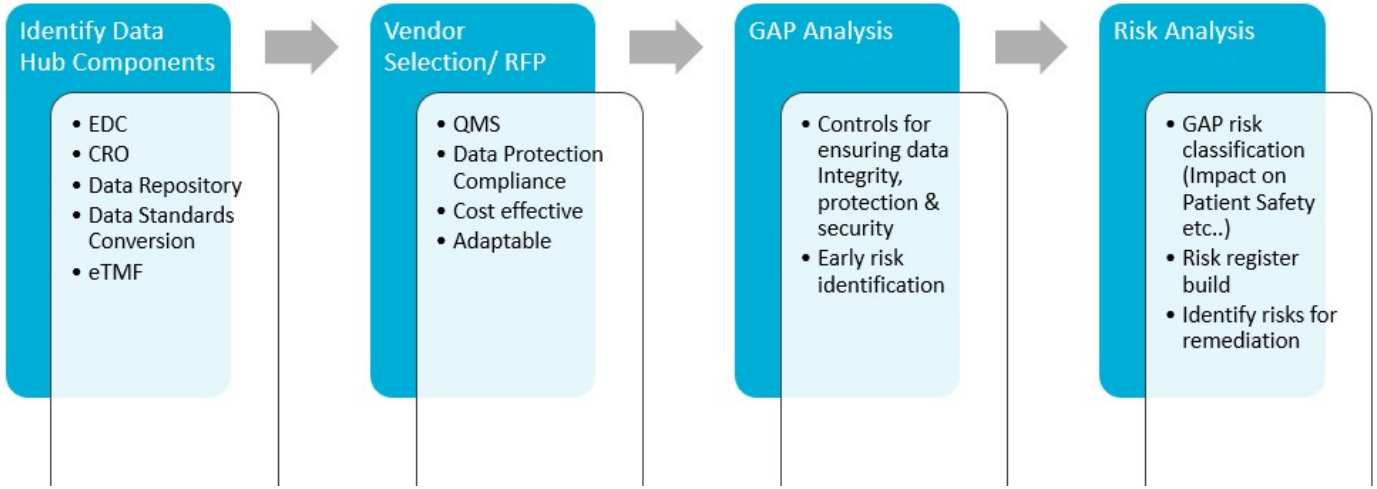
Study Set Up Procedure: Technology Build



Study Set Up Procedure: Compliance

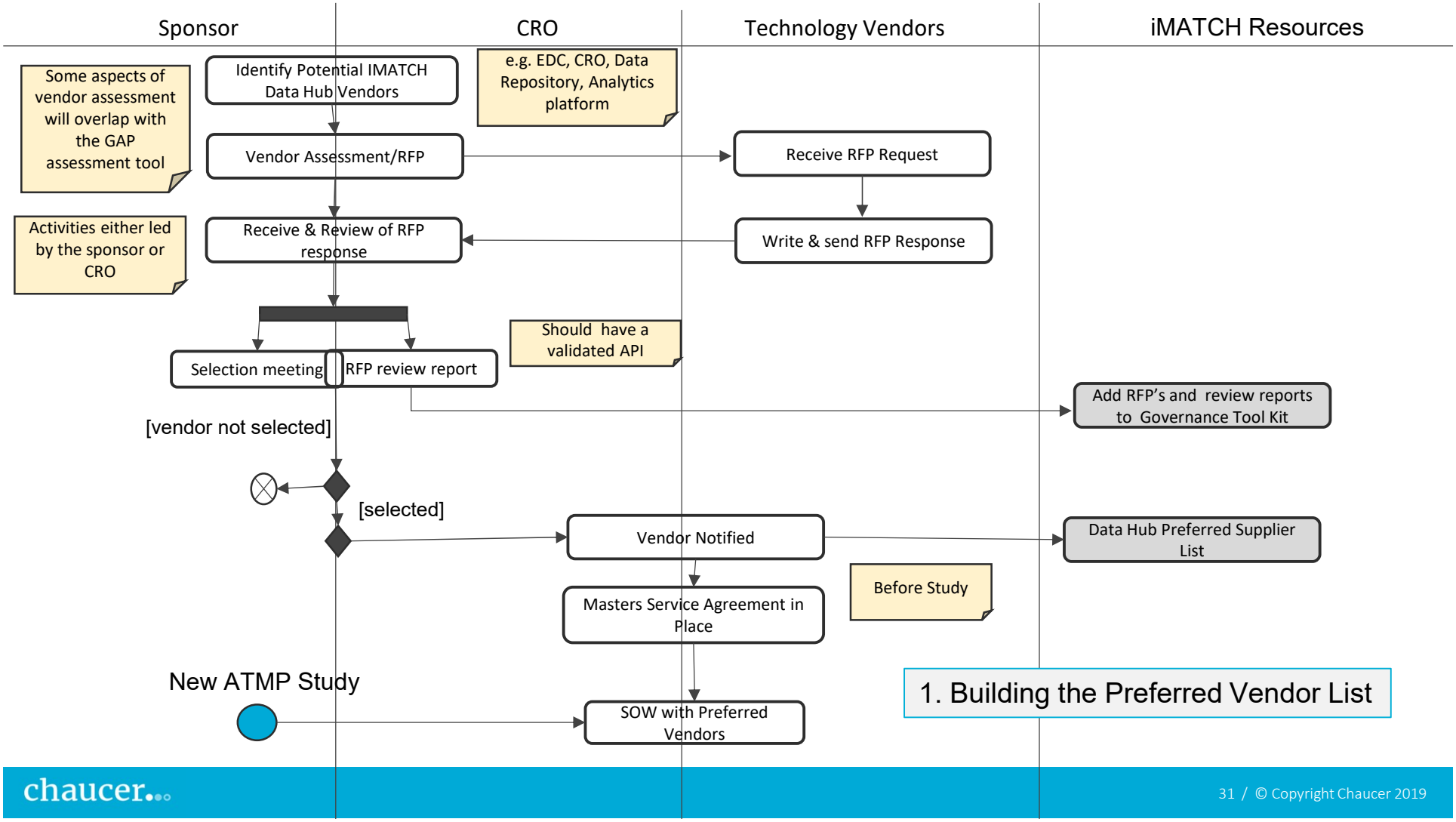


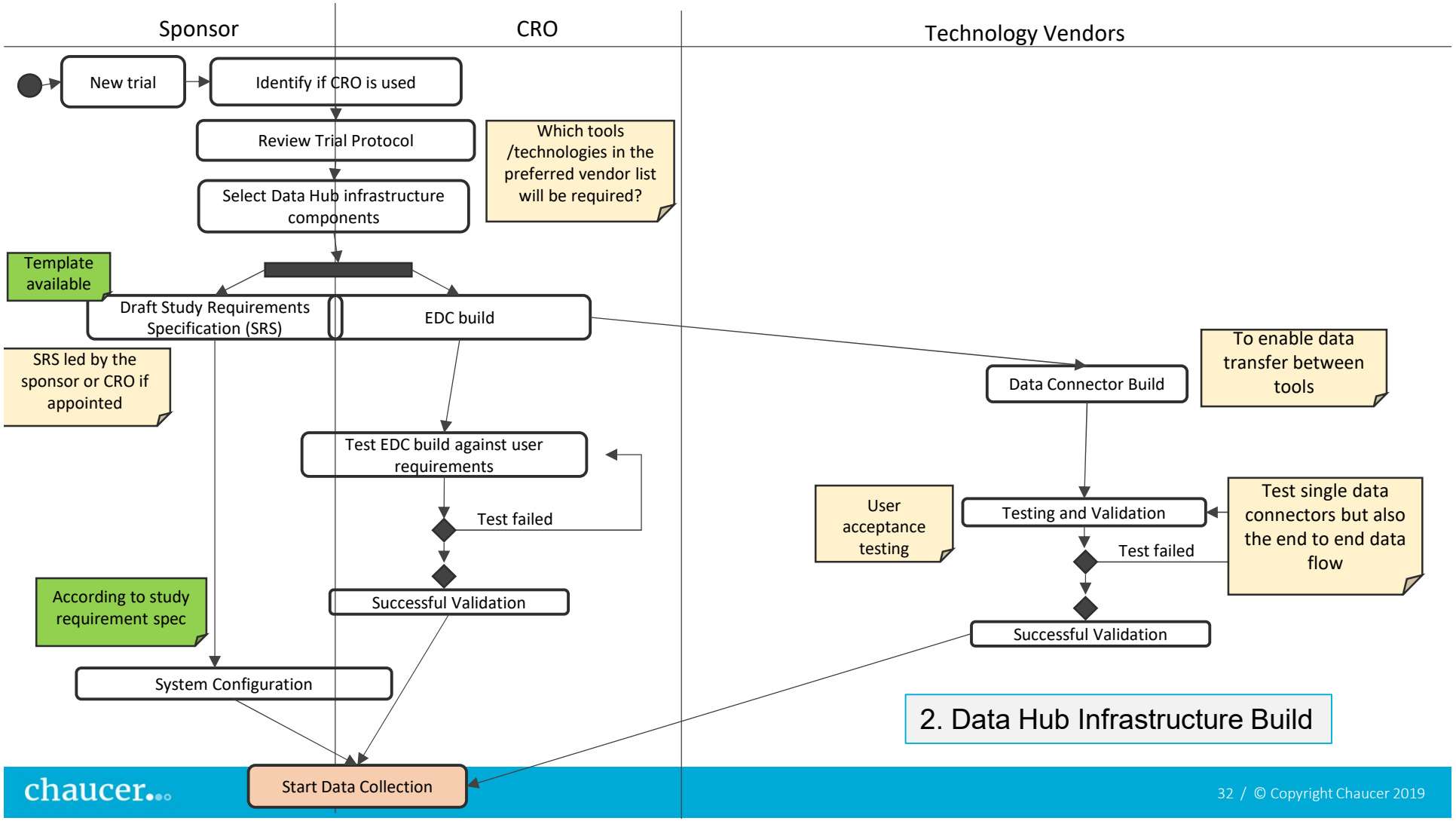
Study Set Up Procedure: Due diligence

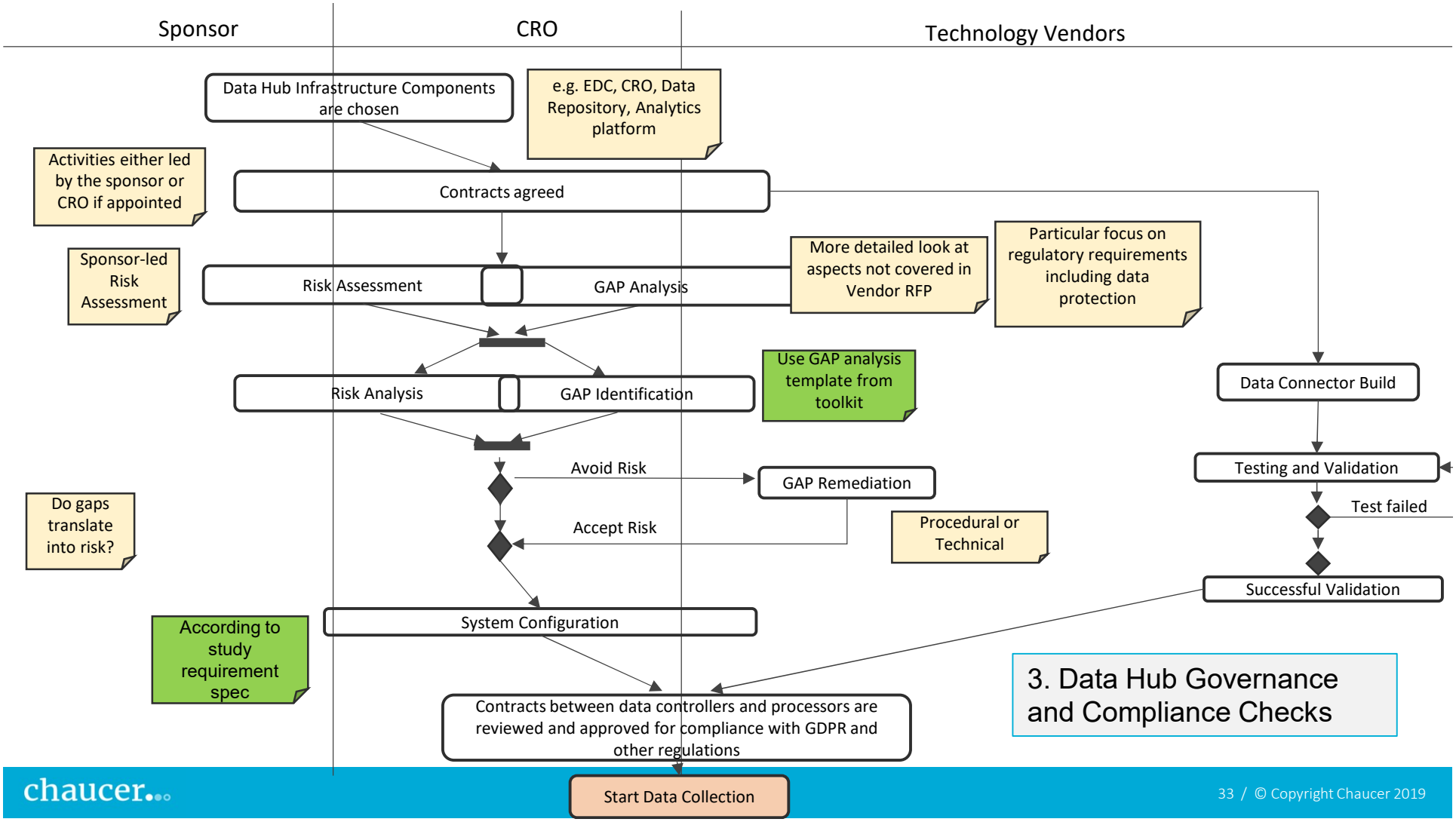


Activity Diagrams : Who does what and when

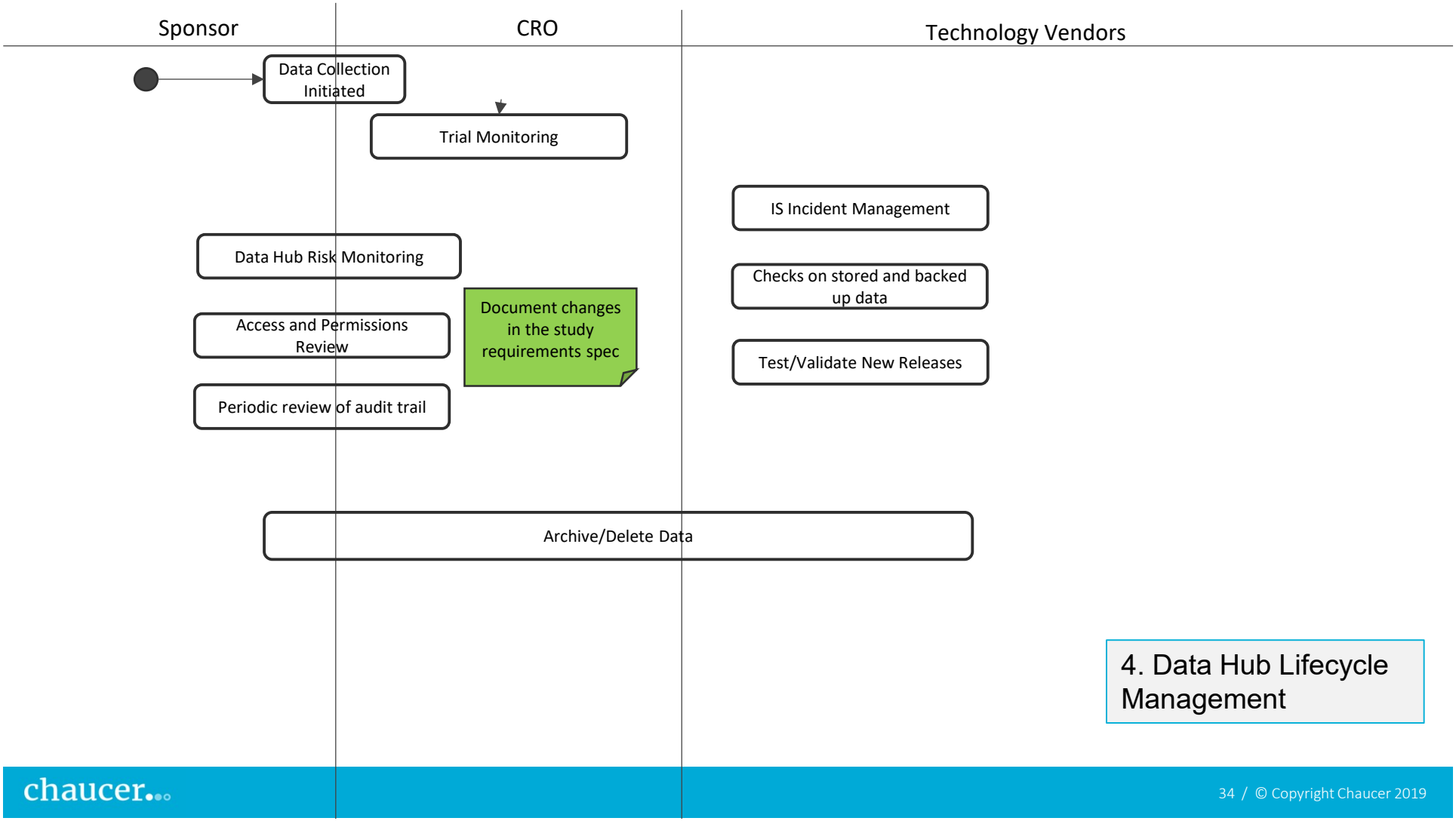
To guide compliance and consistency in study set up


Sponsor
CRO
Technology Vendors
iMATCH Resources
Some aspects of vendor assessment will overlap with the GAP assessment tool
Identify Potential IMATCH Data Hub Vendors
e.g. EDC, CRO, Data Repository, Analytics platform
Vendor Assessment/RFP
Receive RFP Request
Activities either led by the sponsor or CRO
Receive & Review of RFP response
Write & send RFP Response
Should have a validated API
Selection meeting
RFP review report
Add RFP's and review reports to Governance Tool Kit
[vendor not selected]
[selected]
Vendor Notified
Data Hub Preferred Supplier List
Masters Service Agreement in Place
Before Study
New ATMP Study
SOW with Preferred Vendors
1. Building the Preferred Vendor List


Sponsor
CRO
Technology Vendors
New trial
Identify if CRO is used
Review Trial Protocol
Which tools /technologies in the preferred vendor list will be required?
Select Data Hub infrastructure components
Template available
Draft Study Requirements Specification (SRS)
EDC build
SRS led by the sponsor or CRO if appointed
Data Connector Build
To enable data transfer between tools
Test EDC build against user requirements
Test failed
User acceptance testing
Testing and Validation
Test single data connectors but also the end to end data flow
Test failed
Successful Validation
According to study requirement spec
Successful Validation
System Configuration
Start Data Collection
2. Data Hub Infrastructure Build



3. Data Hub Governance and Compliance Checks



4. Data Hub Lifecycle Management

Does the framework deliver?

- Ahead of processing
  - There is a process in place to ensure procedures and policies are in place to minimise risks to data integrity, security and data protection
  - There is clear accountability for trial sponsor and data hub vendors involved in the technology build and operational aspects of clinical data processing
  - Tools are available to identify residual risks that require management.
  - There is reinforcement of the importance of adequate training for staff involved in the data hub on the principles of data integrity
- During data processing
  - The working environment will encourage reporting of issues and errors that occur during data processing
  - There is a recommended process for periodic audits to be conducted to review technologies, incident reports and data stored & backed up
- Completion of processing
  - Checks are carried out to ensure established and compliant procedures are in place for the storage/archiving/deletion of data

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