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Data Governance Planning

PDA 12 May 2015

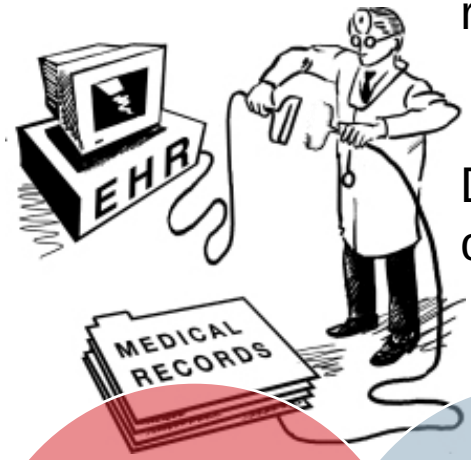
Agenda

- Overview of Data Integrity
- Assurance of Data
- Data Governance
- The Data Governance Plan
- Questions

Overview of Data Integrity

Data

Information derived or obtained from raw data (e.g. a reported analytical result).



Data can be ‘electronic’ or ‘paper based’ or ‘Hybrid’

However all data must be:

A – attributable to the person generating the data

L – legible and permanent

C – contemporaneous

O – original record (or ‘true copy’)

A – accurate

MHRA
Regulating Medicines and Medical Devices

Source: MHRA GMP Data Integrity Definitions and Guidance for Industry March 2015

Data Integrity

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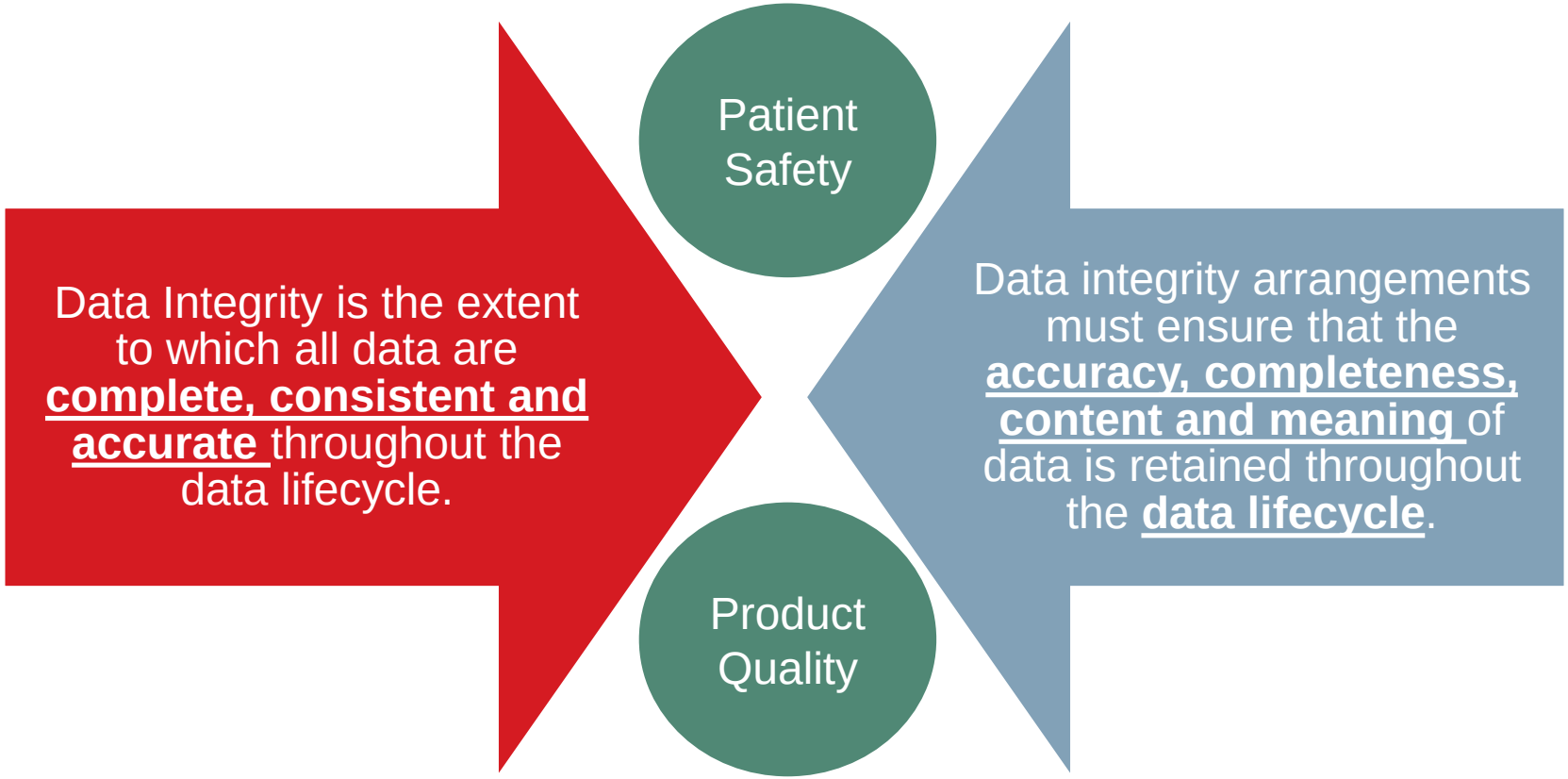


Source: MHRA GMP Data Integrity Definitions and Guidance for Industry March 2015

Assurance of Data Integrity

How do we assure data integrity?

- Application of good documentation practices when using paper based, electronic or hybrid – the same rules apply……..

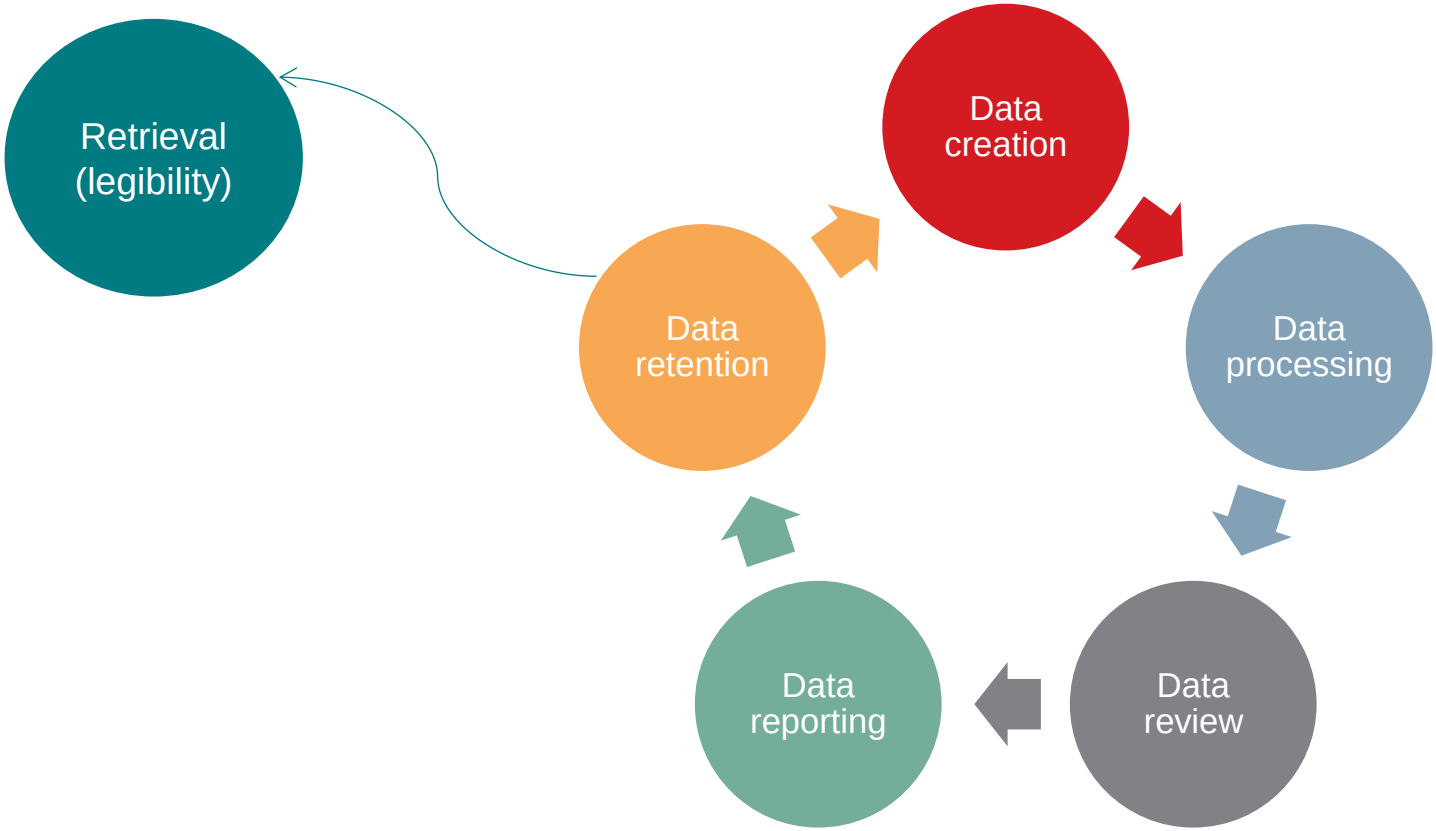
*4.9 Any **alteration** made to the entry on a document should be **signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded.***

*4.7 Handwritten entries should be made in a **clear, legible, indelible** way.*

*4.8 Records should be made or **completed at the time each action** is taken and in such a way that all significant activities concerning the manufacture of medicinal products are **traceable**.*

How do we assure data integrity?

Use and understanding data life cycle management



How do we assure data integrity?

External environmental factors

Control of external environmental factors requires consideration of:

- Increasingly complex supply chains
- Outsourcing of GxP operations
- Economic stressors
- Technological advances – increased use of electronic systems

How do we assure data integrity?

Internal environmental factors

Control of internal environmental factors required consideration of:

- Quality Management Systems
- Adequate understanding and control of computerised systems and paper based recording system
- Senior stakeholder sponsorship of data integrity assurance activities

Data Governance

Data Governance

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The **sum total of arrangements** to ensure that data, irrespective of the format in which it is generated, **is recorded, processed, retained** and used to ensure a **complete, consistent and accurate record** throughout the data lifecycle

Data governance should address **data ownership throughout the lifecycle, and consider the design, operation and monitoring of processes / systems in order to comply with the principles of data integrity** including control over intentional and unintentional changes to information.

Source: MHRA GMP Data Integrity Definitions and Guidance for Industry March 2015

Data Governance

The data governance system should be integral to the PQS

The effort and resource assigned should be commensurate with the risk to product quality

- Should be balanced with other QA resource demands

Note: Data is not homogeneous; therefore, neither is risk this should be considered when assigning resource

The expectation is not to implement a forensic approach to data checking on a routine basis, but to design and operate a system which provides an acceptable state of control based risk

At its best, data governance identifies risk – both business and compliance risk – by increasing oversight

Why Enterprises Struggle With Data Governance

In the financial service industry, where data integrity has been a concern for many years, it has been reported in 2008 less than 10 percent of organizations will succeed at their first attempts at data governance.

This has been attributed to:

- Cultural barriers
- Lack of senior-level sponsorship

This statistic may prove very informative for our industry as we embark on addressing data integrity assurance within our organisations!!

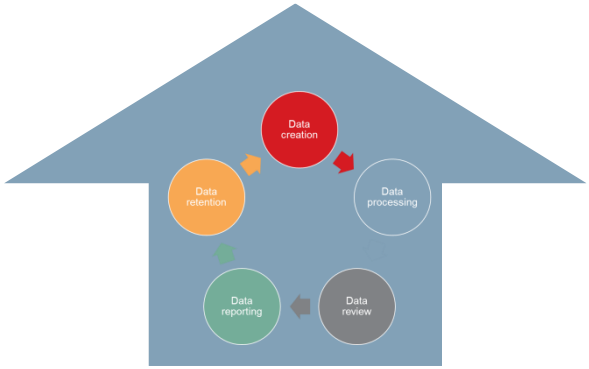
Data Governance – Application

The core of data governance is creating a framework to ensure that data generated is:

- Recorded
- Processed
- Retained
- Used

To ensure data, throughout the data lifecycle, is:

- complete
- consistent
- accurate



Food for thought

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Manufacturers and analytical laboratories should be aware that reverting from automated / computerised to manual / paper-based systems will not in itself remove the need for data integrity controls.

This may also constitute a failure to comply with Article 23 of Directive 2001/83/EC, which requires an authorisation holder to take account of scientific and technical progress and enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods.

Source: MHRA GMP Data Integrity Definitions and Guidance for Industry March 2015

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The Data Governance Plan

Elements to be considered

An overarching data governance system, should include :

Relevant policies, standards

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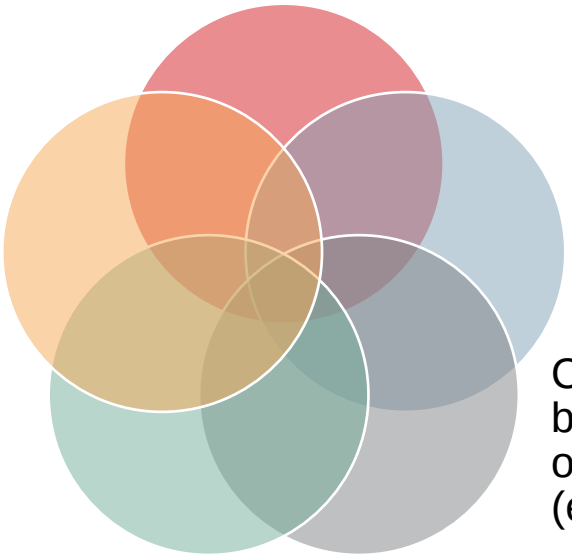
Effort and resource applied should be commensurate with criticality in terms of impact to product quality attributes



Staff training - general & role specific e.g. audit team

Technical controls (e.g. computer system access)

Consideration should be given to the organisational controls (e.g. procedures)

Practical Elements to be considered

Systems should be designed in a way that encourages compliance e.g. :

- **Access to clocks** for recording timed events
- Accessibility of **batch records at locations** where activities take place so that ad hoc data recording and later transcription to official records is not necessary
- **Control over** blank paper **templates** for data recording
- User **access rights** which prevent (or audit trail) data amendments
- **Automated data capture** or printers attached to equipment such as balances
- Proximity of printers to relevant activities
- Access to sampling points (e.g. for water systems)
- **Access to raw data** for staff performing **data checking activities**.

Data Governance Plan

- The Governance Plan should consider the following two elements:
  - Prevention – better than cure!!!
  - Detection – safe guarding the data!!!

Prevention[1]

- QMS modernisation
- CSV
- Data review policy
- Standards
- Vendors (metrics/controls)
- QTAs and templates

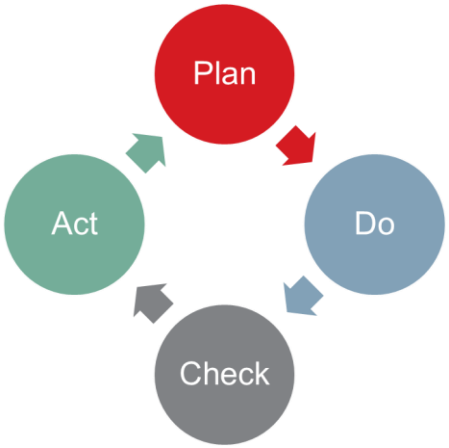
Detection[1]

- Auditing
- Identifying risk factors
- Data review process
- Whistleblower

[1]Not exhaustive lists

Data Integrity Governance Plan

- Require a phased approach to role out –
  - Consider a PDCA model

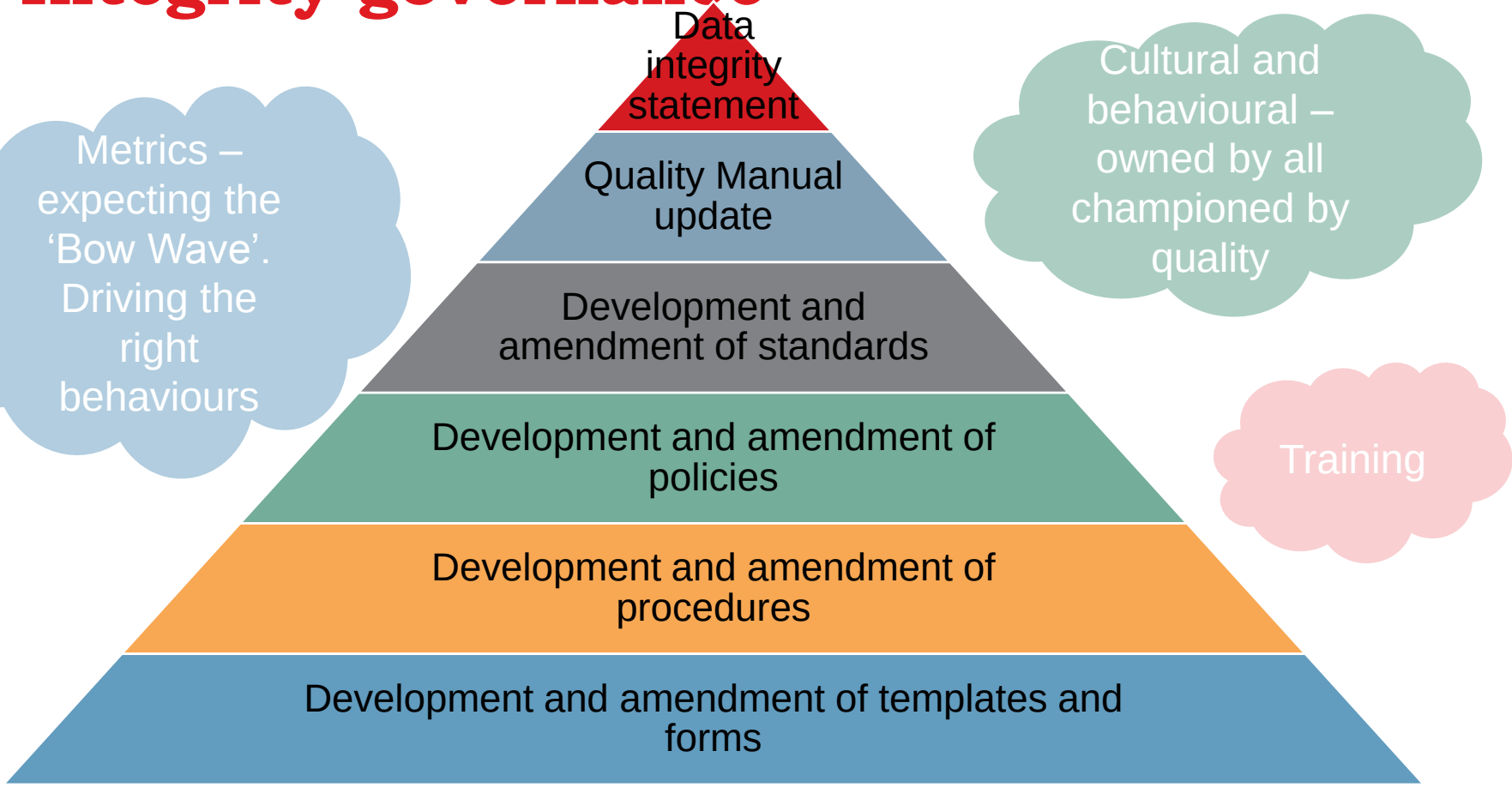


Data Integrity Governance Plan- Phase 1

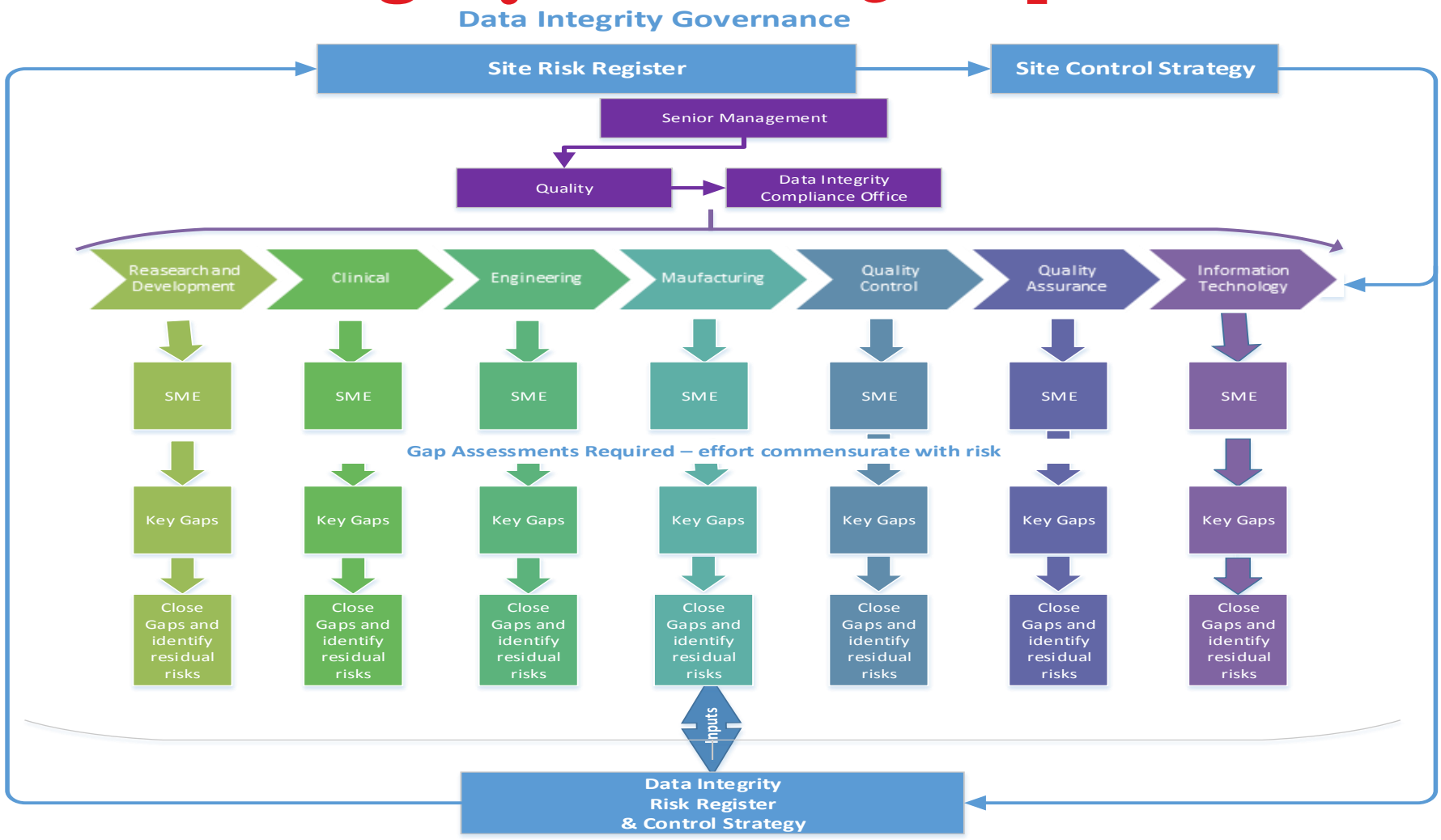
Phase 1 - Plan | Phase 2 - Do | Phase 3 - Check | Phase 4- Act

- Define a governance structure
  - Governance at ‘senior level’, roll out a ‘grass roots’
  - Appoint a Data Integrity Compliance Officer – not owner!!!
- Gain buy in from SLT & senior stakeholders
- Communications plan
- Education up and down the organisation
- Market the project to instil the appropriate culture and bring awareness
- Develop Metrics for tracking (project and DI)
- Develop a ‘Tool Kit’
  - Glossary and definitions (common language)
  - Policies
  - Standards
  - Procedures
  - Whistle blowers charter and structures
  - Templates – Gap Assessments, URS, SLAs, Validation, QTA, Audit etc.

PQS – updates to support Data Integrity governance



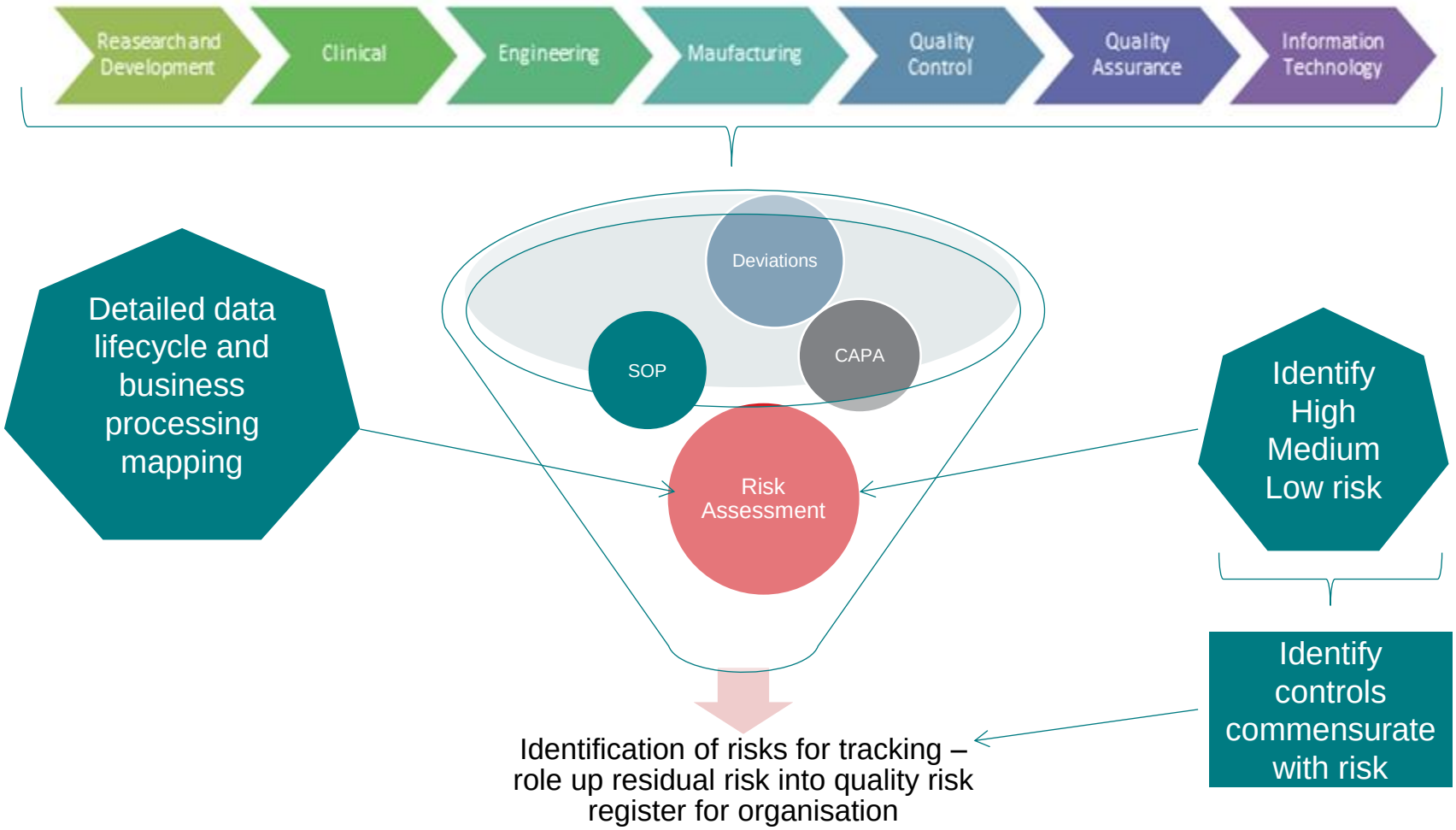
Data Integrity and the QRM process



Data Integrity Governance Plan- Phase 2

- Roll out the plan
  - 'line in the sand'
- Mandated to each of the functional groups
  - SMEs for actioning the activities
- Complete a Gap Assessment of current state against the ideal
  - Horizontal Cut
    - Qualitative assessment
    - Identify low, medium and high risk areas
  - 'Deep Dive' for the Medium, and High Risk areas – commensurate with risk in the form of formal risk assessment
    - Data lifecycle and business processing mapping

Data Integrity Governance Plan- Phase 2



Data Integrity Governance Plan- Phase 3 & 4

- Check – Phase 3
  - Governance team provide tracking and oversight during 'do' phase – tracking against project roll out
  - Important to understand that in the initial phase metrics may appear to look worse as issues are detected through the gap assessment and QRM activities
    - Communication of this potential 'Bow Wave' effect is important
  - Quick wins actions
  - Long term actions
- Act – Phase 4 – Sustain
  - Incorporate DI metrics into the Quality Management Review process and track
  - Incorporate DI into the self inspection & vendor qualification and oversight programs

Summary

Summary

Overview of Data Integrity

- Applies to all data sources
- Patient Safety and Product Quality

Assurance of Data

- Paper based, electronic or hybrid – the same rules apply (ALCOA)
- Assuring appropriate data life cycle management
- Identifying and controlling internal and external factors

Data Governance

- The core of data governance is creating a framework to ensure that data generated is recorded, processed, retained & used to ensure complete, consistent & accurate throughout the life cycle
- Cultural barriers and lack of senior-level sponsorship may be potential obstacles
- Reverting from automated / computerised to manual / paper-based systems will not in itself remove the need for data integrity controls

The Data Governance Plan

- Should consider prevention and detection
- Relevant policies, standards, staff training, consideration should be given to the organisational controls , technical controls
- Effort and resource applied should be commensurate with criticality in terms of impact to product quality attributes
- Governance at a Management Level and roll out at a grass roots
- Things may appear worse before they get better – metrics
- PQS, QRM and QMR

Questions?

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