

PP25 Eminent Transitional Approach to Data Management: A Data Strategist Journey from QbD to Reporting



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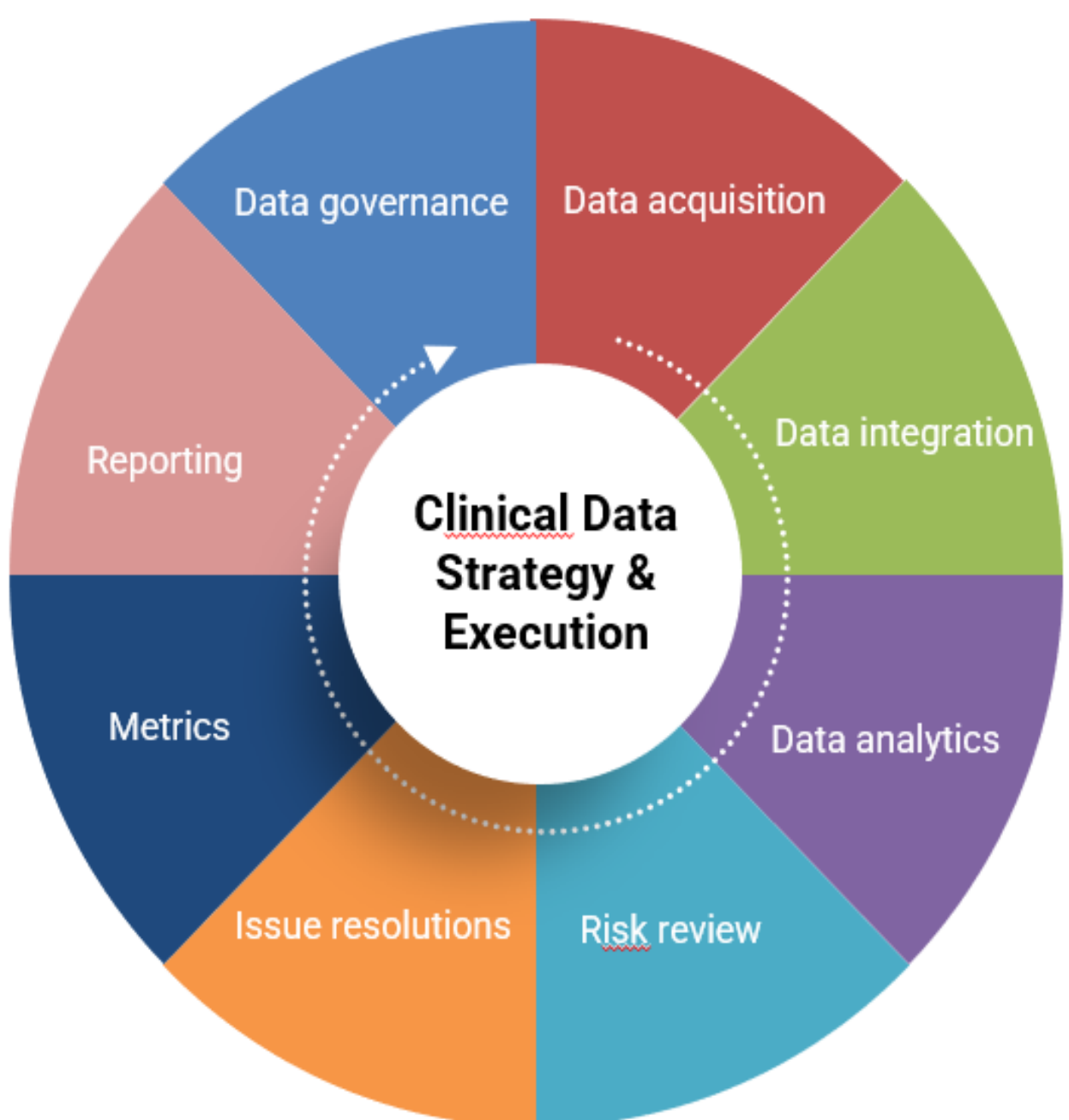


1. Introduction



Complexities with clinical data is an ever-increasing challenge with multiple data points and disparate sources. Almost 60% of data collected from a clinical trial is from external or non-EDC sources. As data management becomes more dynamic with data coming in from various sources like devices/wearables, eCOA, labs, and multiple vendors, the need for central consolidation becomes all the more important. Traditional data management practices rely on a one-size-fits-all approach and lack adequate oversight. In addition, clinical data managers need to be prepared ahead of time to support ever-changing needs. With this background, we are proposing a transitional approach wherein the role of data managers evolves to data strategists, thus positively impacting preparedness.

2. Clinical Data Strategy & Execution



An alternative approach to traditional data management involves the creation and execution of a robust data strategy, consisting of the following 8-step iterative steps:

- 1. Governance:** Defining and understanding key steps of the data lifecycle. This includes quality by design (QbD), critical to quality factors (CtQs), and proactive risk management.
- 2. Data acquisition:** A robust and open discussion about data acquisition planning must start from the protocol development stage which can be cascaded into an effective data acquisition model
- 3. Data integration:** Right from data accrual, effective data integration planning must be in place. This includes the creation of a data flow map and systems that can pull in data from disparate sources
- 4. Data analytics:** Building state-of-the-art data analytics capabilities for near-real-time and automated data reviews, to ensure patient safety and data integrity across the trial duration
- 5. Risk review:** Risks identified via data signals by different cross-functional groups should be reviewed at regular intervals to plan titration of mitigation plans
- 6. Issue resolution:** An effective issue resolution mechanism via signal journey must be implemented. This can help course correct data issues and mitigate risks in a timely manner
- 7. Metrics:** To review quality goals, a set of operational and quality metrics must be in place to ensure benchmarks are being met and any associated actions are identified.
- 8. Reporting:** All reporting elements such as data governance strategy, plans, data signals, and risks can be synthesized into clinical study reports

3. Data Manager to Data Strategist

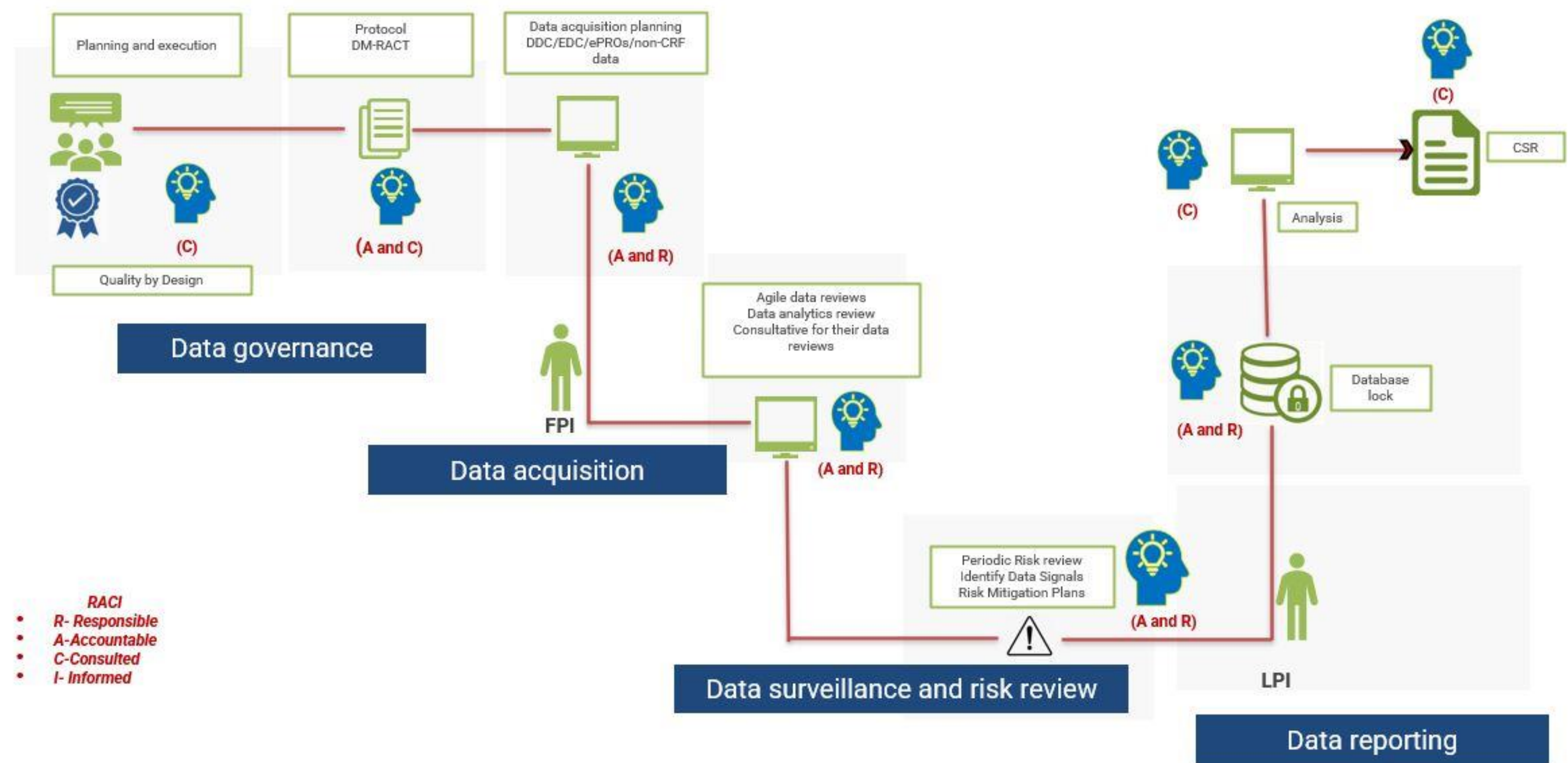


Role	Gap analysis of skillset mapping						
	Data governance	Data acquisition	Data integration	Data analytics	Risk review	Issue resolution	Quality metrics
Current data managers							
Data strategists (Expected change)							

No competence Low competence Some competence High competence Expert

The chart shown above is a depiction of the gap analysis between the current skillset of data managers versus what is expected of data strategists. Based on our evaluation, to make this transition possible upskilling in certain areas is a must.

4. Data Strategist Journey



5. Conclusions



Transitioning from traditional data management to data strategy is the need of the hour. This shift requires a 360-degree change in data governance, ownership, and accountability. For this to be effectively executed, the preparedness of current and upcoming clinical data managers is the key consideration. With this paper, the goal is to understand what data strategy involves and the path ahead for data managers transitioning to data strategists. With upskilling, data strategists will play an important role in addressing challenges arising from data sharing, collaboration with different teams, and vendors, real-time data visualization, and risk assessment insights. Change is always difficult although this shift in data management practices will truly help researchers overcome data challenges of the future effectively.