



De-centralized clinical data management

An innovative 3-way approach
(risk-data-analytics) to protect
data integrity

Presenter:

Nithiya Ananthakrishnan
Founder and CEO,
Algorics

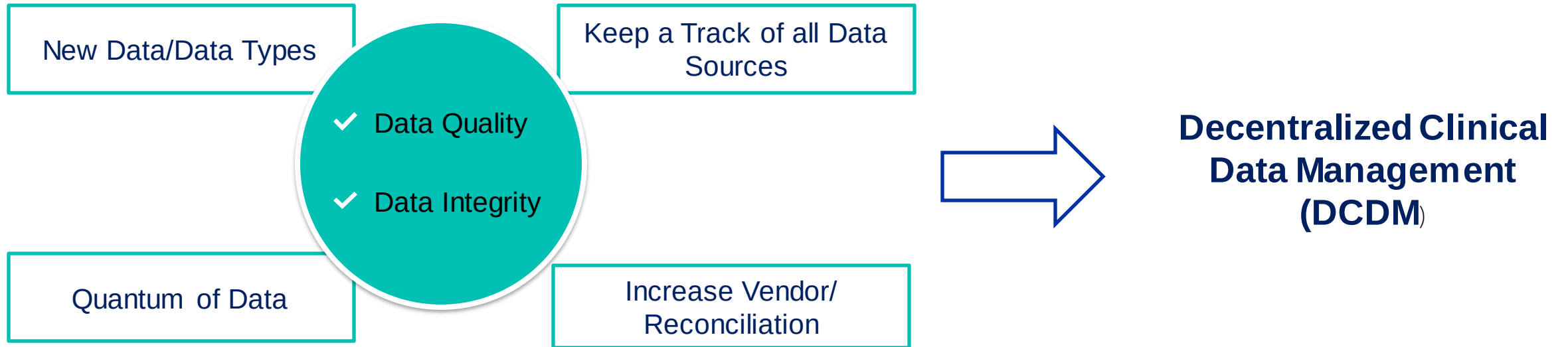


Agenda

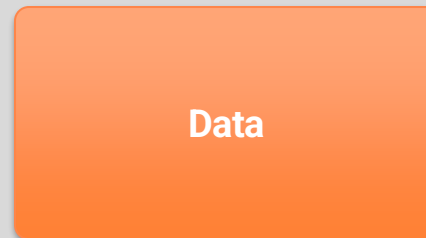
1. Decentralized Data- Key Challenges
2. Decentralized clinical data management- Approach
3. 3-Way approach
 - Risk: Risk Assessment and Mitigation Strategies
 - Data: Acquisition and Integration
 - Analytics: Data Review and Decision making
4. Key Takeaways

Decentralized Data- Key Challenges

“How” to manage the data from decentralized Trials.



Centralizing data management approach



Strategic & enabling pillars

Risk Assessment

Risk Mitigation
Strategies

Data acquisition

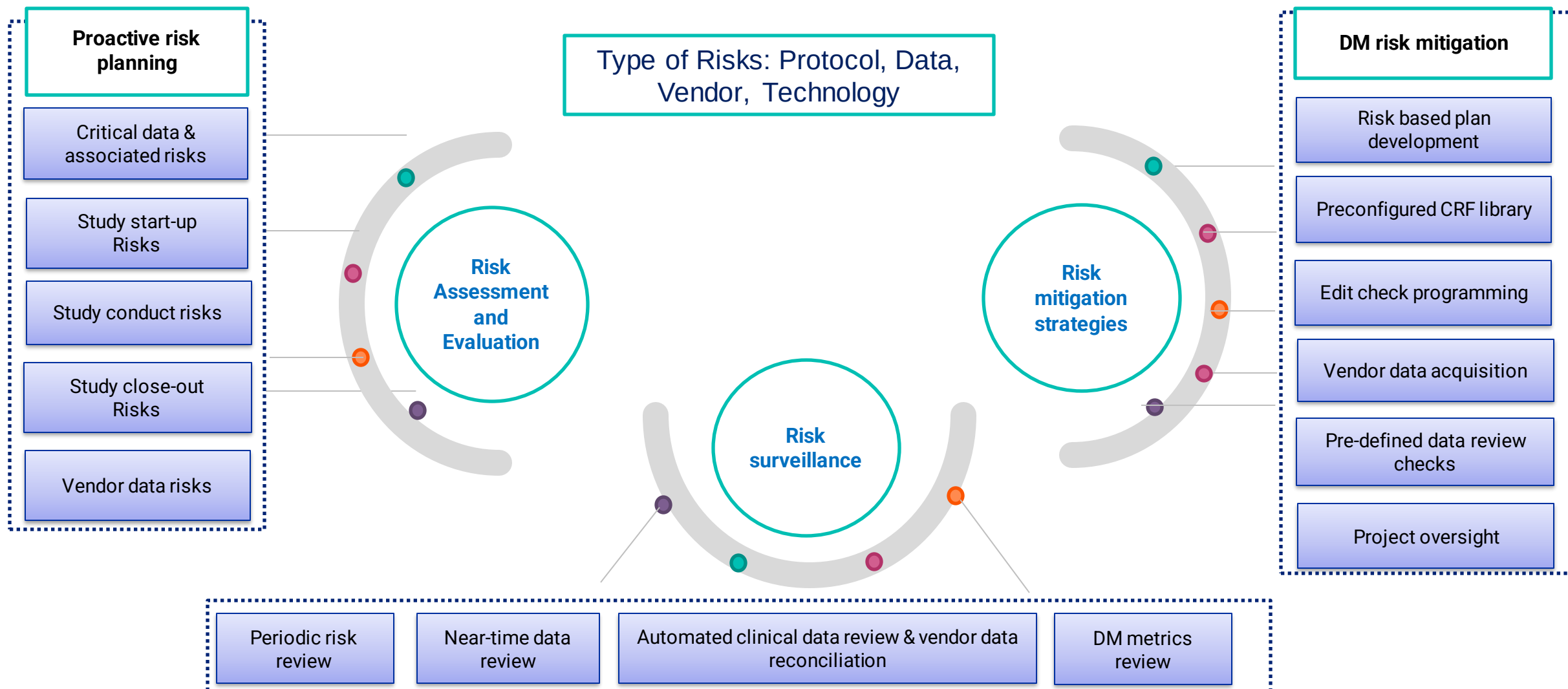
Data integration

Agile clinical data
review

Data-driven
decision making

Data Quality & Data Integrity

Risk Assessment and Mitigation Strategy

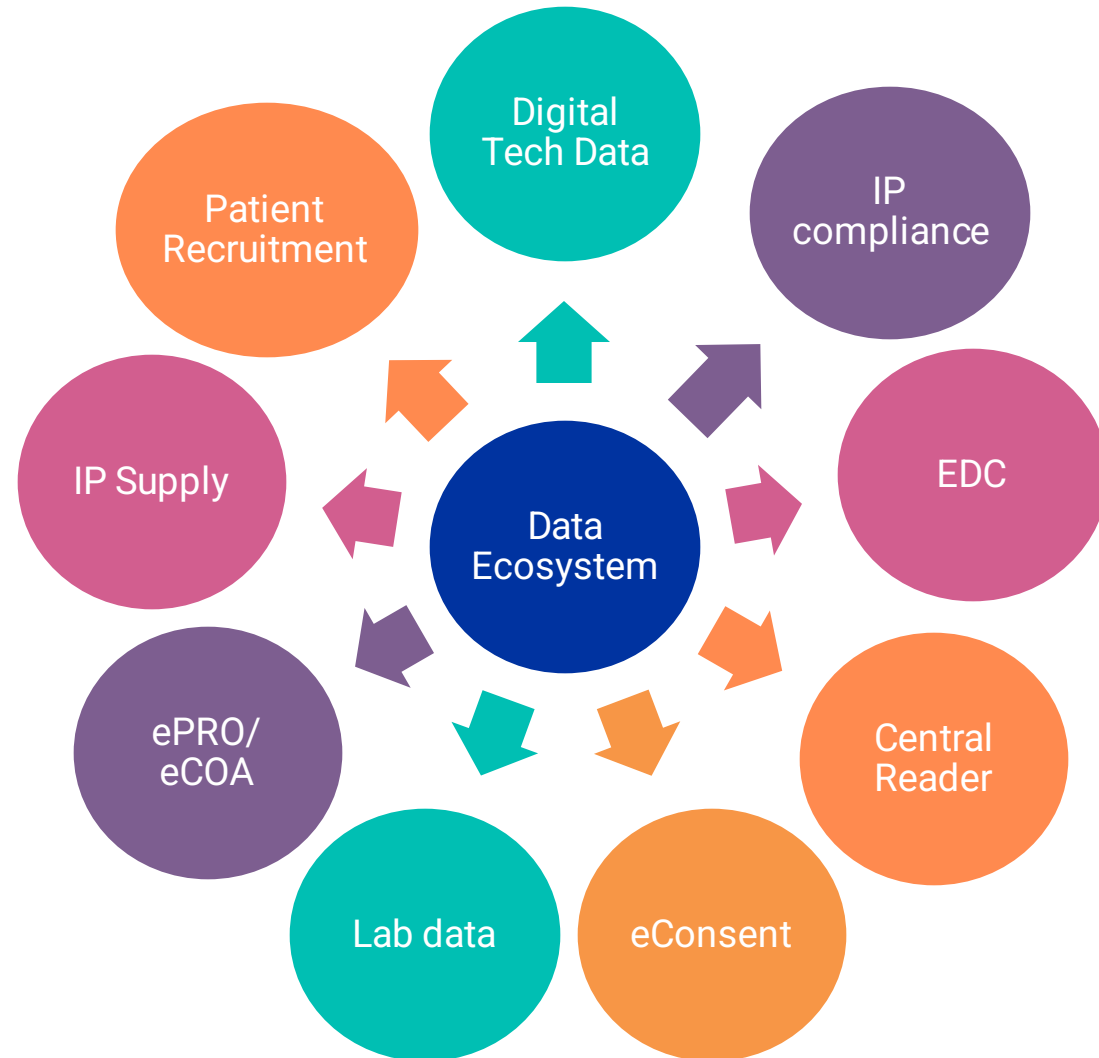


DM RACT Examples

DM-RACT: Risk Assessment and Control Matrix helps us to identify the risks associated data, system and protocol-specific risks

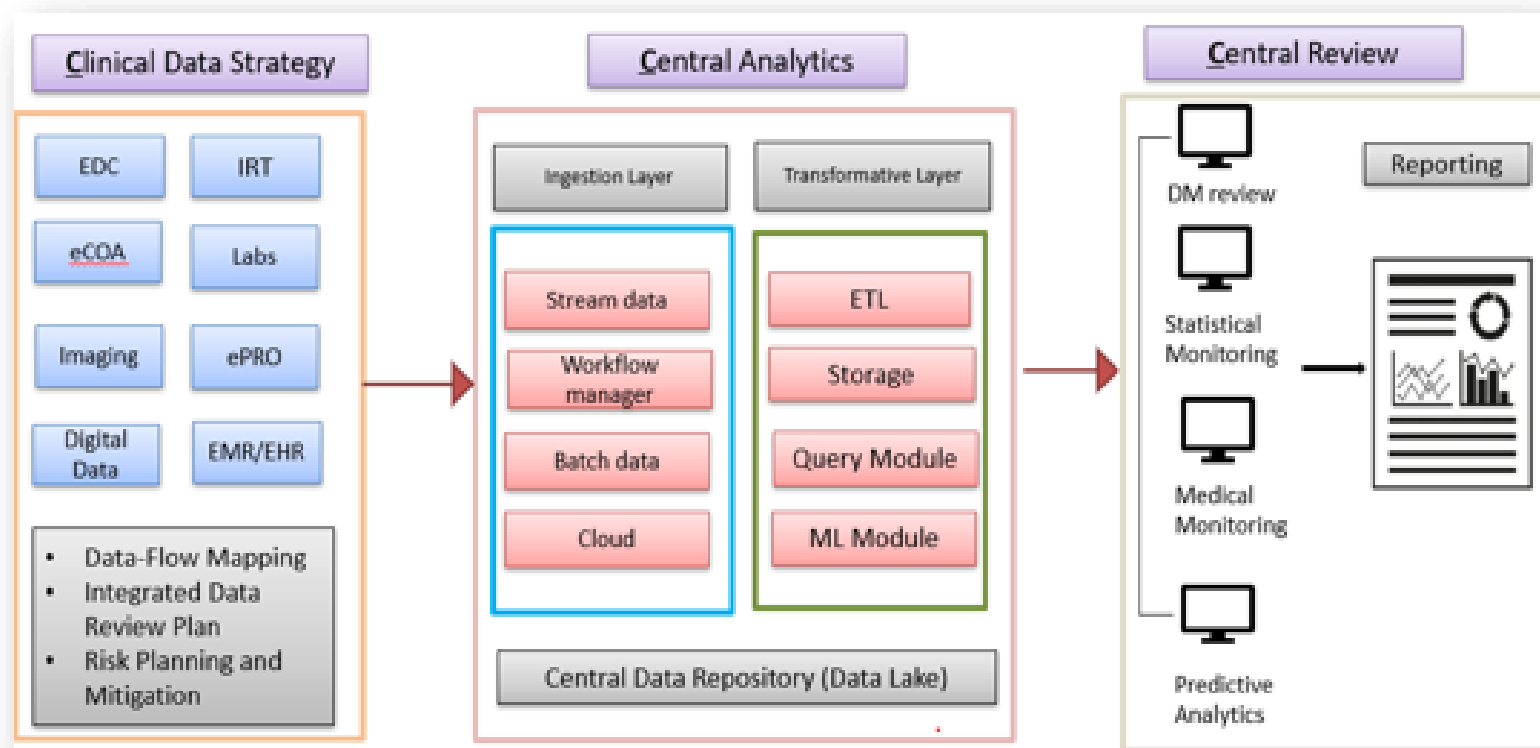
 Category	 Description	 Category	 Mitigations
Critical data risks	If there are missing tumor evaluation data, it might impact evaluation of primary endpoint	High	DM ensures all the tumor evaluation data as per protocol; edit checks for possible cases; DM will review tumor data at frequent intervals
Start-up risks	If the database visit matrix is not matching with the protocol SOE, it might impact the data collection leading to inadequate data quality	High	DM will review database visit matrix before set-up; DM programming team will perform internal QC
Study conduct risks	If there are a high volume of outstanding queries, it might impact overall data cleaning and data quality	Medium	DM will review periodic query review meeting with sites; site training on query resolution..
Study close-out risks	If the PI signature on EDCs is not completed on time, it might impact DBL timelines	High	Site training on PI oversight and final signature requirement; DM runs metrics around pending signature forms at regular intervals.
Vendor specific risks	If the vendor data review datapoints/variables are not predefined, then it might delay the vendor data reconciliation impacting the data integrity	Medium	Vendor data specification document prepared and reviewed. Pre & post transfer checklist to be deployed

Data Acquisition



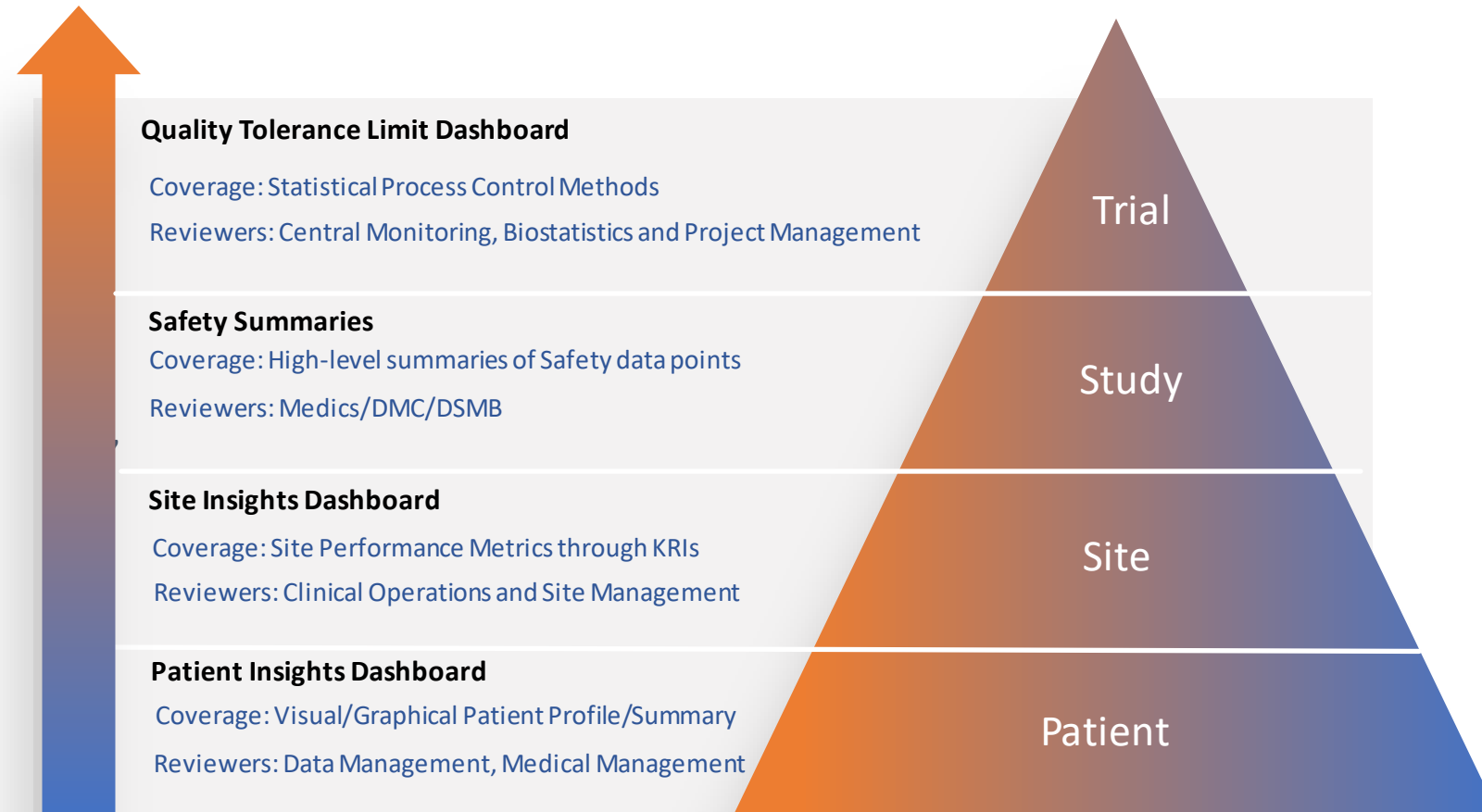
- Data Flow mapping must be established before the start of the trial.
- Data Flow mapping would include all the patient data sources and its format.
- Central Consolidation through Data integration must be considered whenever the use of devices/wearables, eCOA, labs, and numerous vendors, have highlighted the necessity for central consolidation.
- Evaluation of the risk of data loss and mitigations while setting up the system.

Data Integration for Analytics



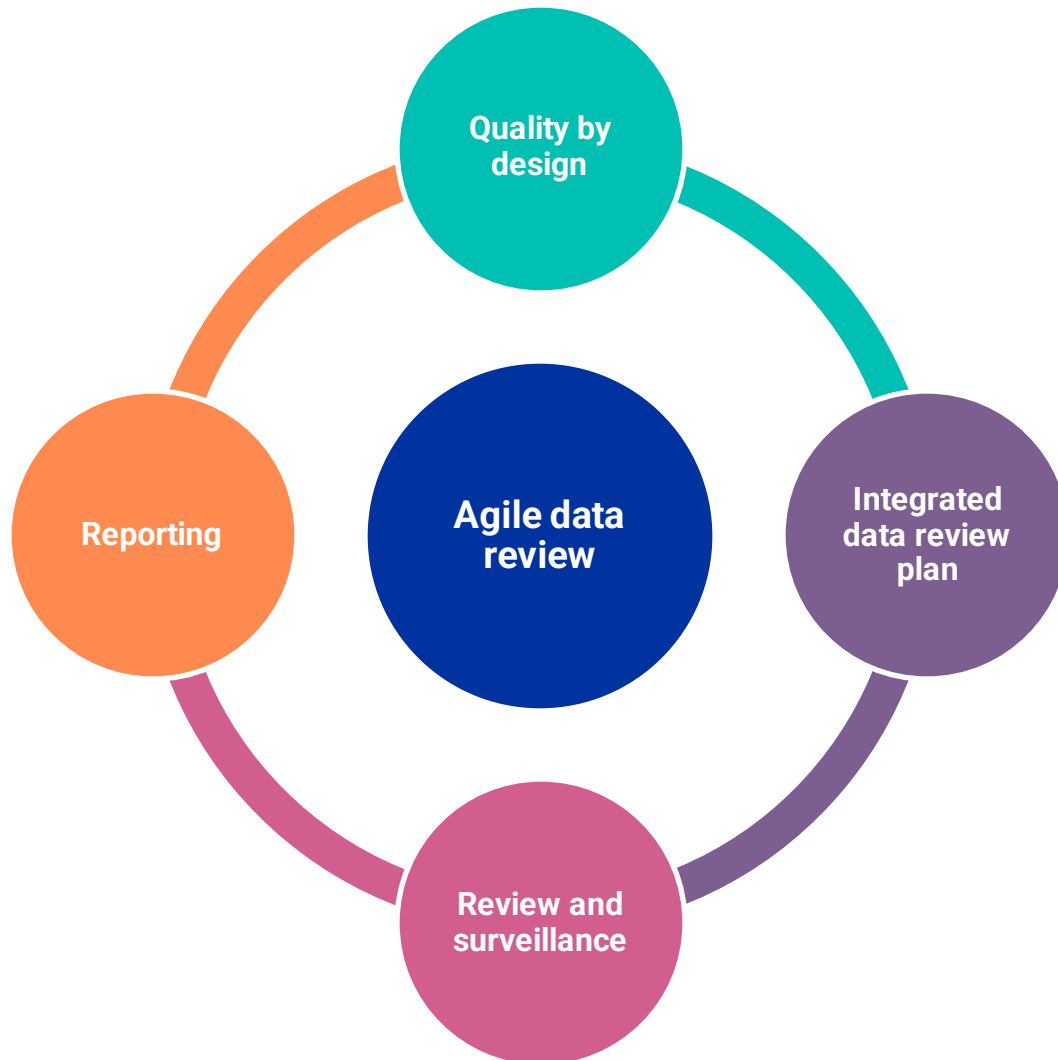
- Building a robust data strategy using big data architecture
- Clear data Strategy for centralizing the data for analytics purposes
- Use of Data Lake for storage of data for reusability

Building Analytics using Integrated Data Review Hierarchy



- Data-driven decision-making (E.g., Risk Mitigation)
- Ready to deploy analysis catalog library with robust architecture and scalable design
- Reduction in manual review through the semi-automated signal trigger mechanism
- Data Review Hierarchy (Patient, Site, and Study addressing various Clinical Stakeholder's needs.

Agile clinical data review process- Plan and Execution



- A data review RACI matrix: defining the who, what, and when across all cross-functional central data review groups (data management, medical affairs, safety management, central monitoring)
- Leveraging an analytics platform built on the concept of the “hierarchical review pyramid” to monitor data integrity and quality. This can deliver multidimensional insights at patient, site, study, and trial levels.
- All central data review groups to discuss signals generated across, review existing risks and anticipated new risks. For existing risks, a review of root causes, actions, and follow-up can be thus planned and executed.

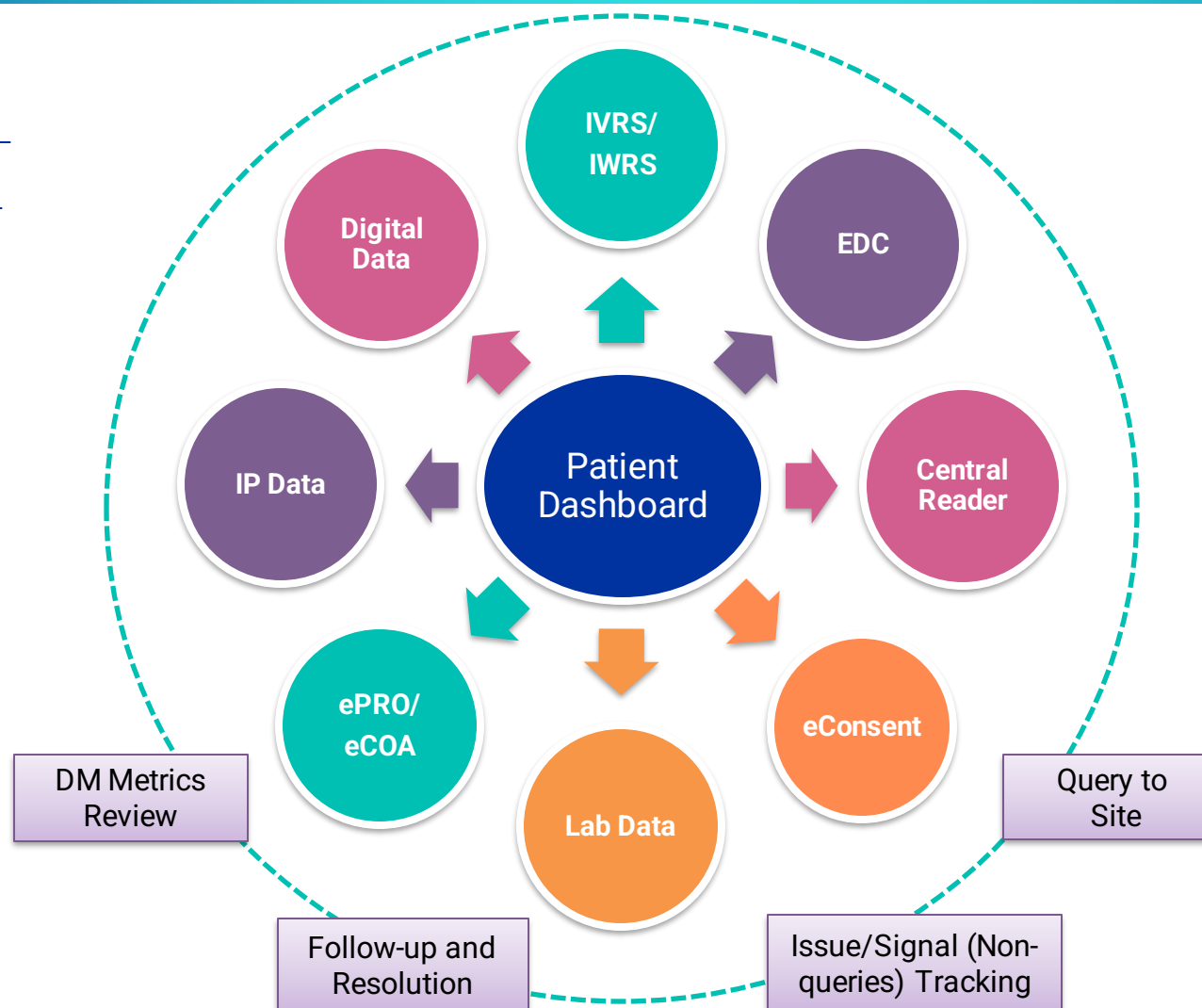
Data-driven decision-making

Visual display of data

Visualization of data holistically allows us to access, review and monitor data effectively

Near real time data reviews

Provides an ability to review the data nearly real-time for early identification of data anomalies that will help timely resolution



Automated DM reviews

Provides continuous surveillance of the data and nearly-automated solutions to reduce manual listings and vendor reconciliation efforts

Vendor reconciliation

Manual efforts on Multiple Vendor Data Reconciliation can be brought into Patient Dashboard and signal triggers can be set up.

Achieve clinical data excellence through futuristic data management models such as D-CDM by

- Using a 3-way (Risk-Data-Analytics) approach with 6-Strategic pillars to manage the Decentralized Data
- Adopting a risk-based approach to data management
- Analytics platform to be built based on Data review Hierarchy principles.
- Use of right technology and architecture
- Adopting Agile Data Review for enhanced risk surveillance
- Upskill data managers

Presenters:

Nithiya Ananthakrishnan
Founder and CEO
E: nithiya@algorics.com
www.algorics.com

Mukesh Babu K
Head of Clinical & Data Operations
E: mukesh.babu@algorics.com
www.algorics.com

THANK
YOU
FOR
YOUR
ATTENTION