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Data Standardization and Integration: Turning Data Chaos into Data Intelligence

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Meet the Speaker

Nisi Nazim

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Nisi Nazim, is responsible for delivering system enhancements and process improvements for the electronic Trial Master File (eTMF) by partnering with business stakeholders and understanding business drivers, system gaps and assessing analytical needs. Prior to BeiGene, at Daiichi Sankyo, Nisi led integration project between eTMF and other systems including CTMS and was a core team member for the Master Data Management initiative and while with Accenture, Nisi contributed towards the implementation of various clinical systems.

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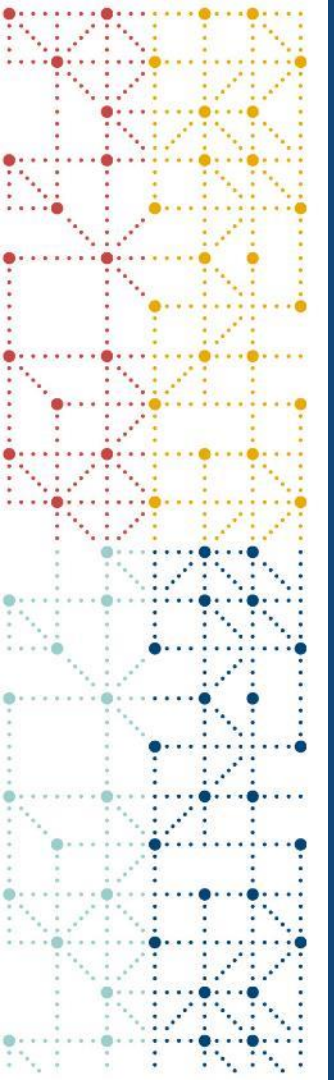
3. Drivers for Integration
4. Integration Journey
5. Case Study & Lessons Learned
6. Tips for Successful Integration



Introduction

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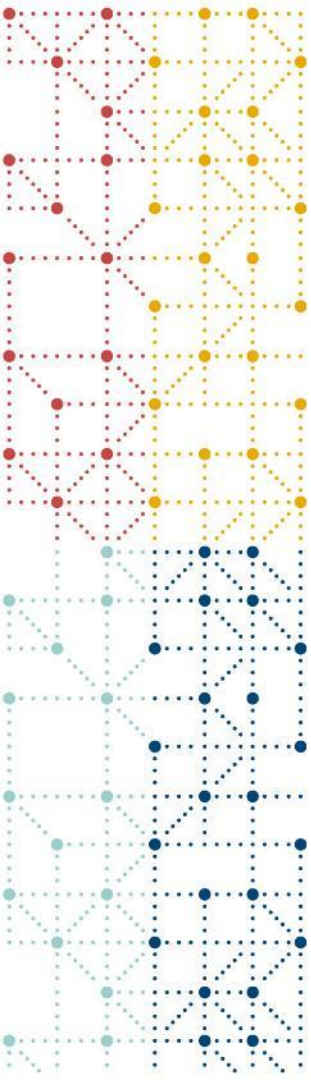
Data and Digital Society

A decade or so ago, regulated processes were governed on paper. Since then, we have evolved in technology, having more electronic data transfers and system-to-system integrations. Retention periods have also changed significantly.

The pharmaceutical industry and regulatory agencies need accurate and reliable data to ensure safety, efficacy and quality of a product.



Data Standardization

Interpret the date….

05-09-03

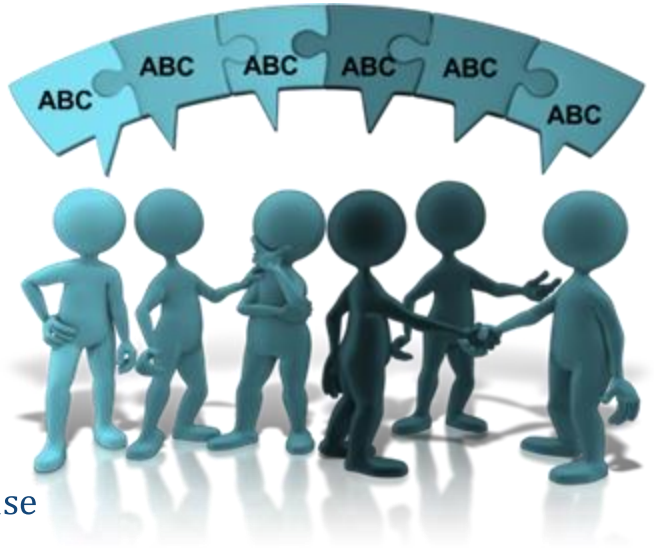
Data Standardization

Data Standardization is the process of making information consistent.

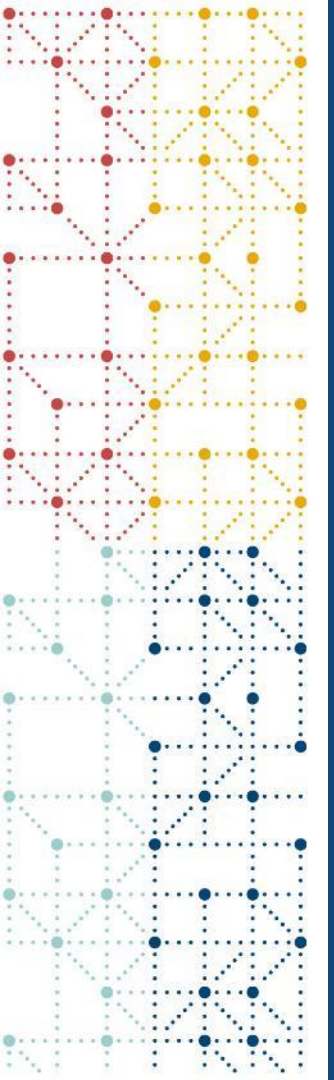
Data standardization is essential for preserving data quality. When data is standardized, it is much easier to detect errors and ensure that it is accurate. This is essential for making sure that decision-makers have access to accurate and reliable information.

Standardization of data :

- Enables **traceability** and data links across systems
- Enables **efficiency** gains related to time-intensive processes involving acquisition, aggregation, analysis and report preparation
- **Eliminate the expense** and time of reformatting data for transfer
- **Enhanced clarity** across third-party organizations and in-house teams
- **Increased opportunity for automation** and advanced software use



How to Standardize your data?



Drivers for Integration

Drivers for integration

There are multitude of electronic clinical solutions to help simplify the clinical trials process. These solutions provide benefits for specific aspects of the clinical trial process. As the number of clinical systems and the demand for efficiency increases, there is a growing need to share data.

Based on surveys, standalone eClinical applications including EDC (91%), eTMF (78%), and CTMS (64%), are now utilized by most sponsors and CROs as they steadily adopt function-specific technologies to better automate clinical trials[1].

Most (98%) CRO respondents say they need to improve information sharing between study partners to reduce manual processes (78%), speed trials (61%), and improve collaboration (57%)[2].

1 - Veeva 2020 Unified Clinical Operations Survey: Annual CRO Report
2 - Veeva-2020-Unified-Clinical-Operations-Survey-Report

Drivers for integration

Challenges with fragmented systems and processes:

01 Duplication of data

02 Lack of data integrity

03 Increased manual effort

04 Managing / reconciling trial information across applications

05 Resource constraints and cost implications

Siloed systems and processes lead to:
Lack of visibility in study progress and ultimately slower study execution

Drivers for eTMF integration

An efficient and compliant eTMF must work in harmony with a variety of eClinical systems in order to contain the required information.

Completeness and accuracy of the TMF is a significant regulatory requirement. Therefore, documents must be available in a timely manner for defined milestones with the aim to maintain the TMF "**inspection ready**".

Drivers for eTMF integration

Some of the clinical systems that provide data or documents to eTMF include:

CTMS

- Source of descriptive data
- Milestones
- Documents such as monitoring reports

Safety

Source for safety distribution documents such as Safety Notification Letters, Investigator Brochures and Dear Investigator Letters

Regulatory

Documents such as protocols, study reports, 1572

Benefits of integration

Reduced manual processes.

Increased stakeholder engagement

Increased trial oversight

Improved study quality

Increased data integrity and compliance.

Integration Journey

Integration Journey

Understand your data points

Increase the ‘data’ value by associating data across systems. Getting an understanding of your data, within and across systems, is the single, most important factor in making your data aggregation work

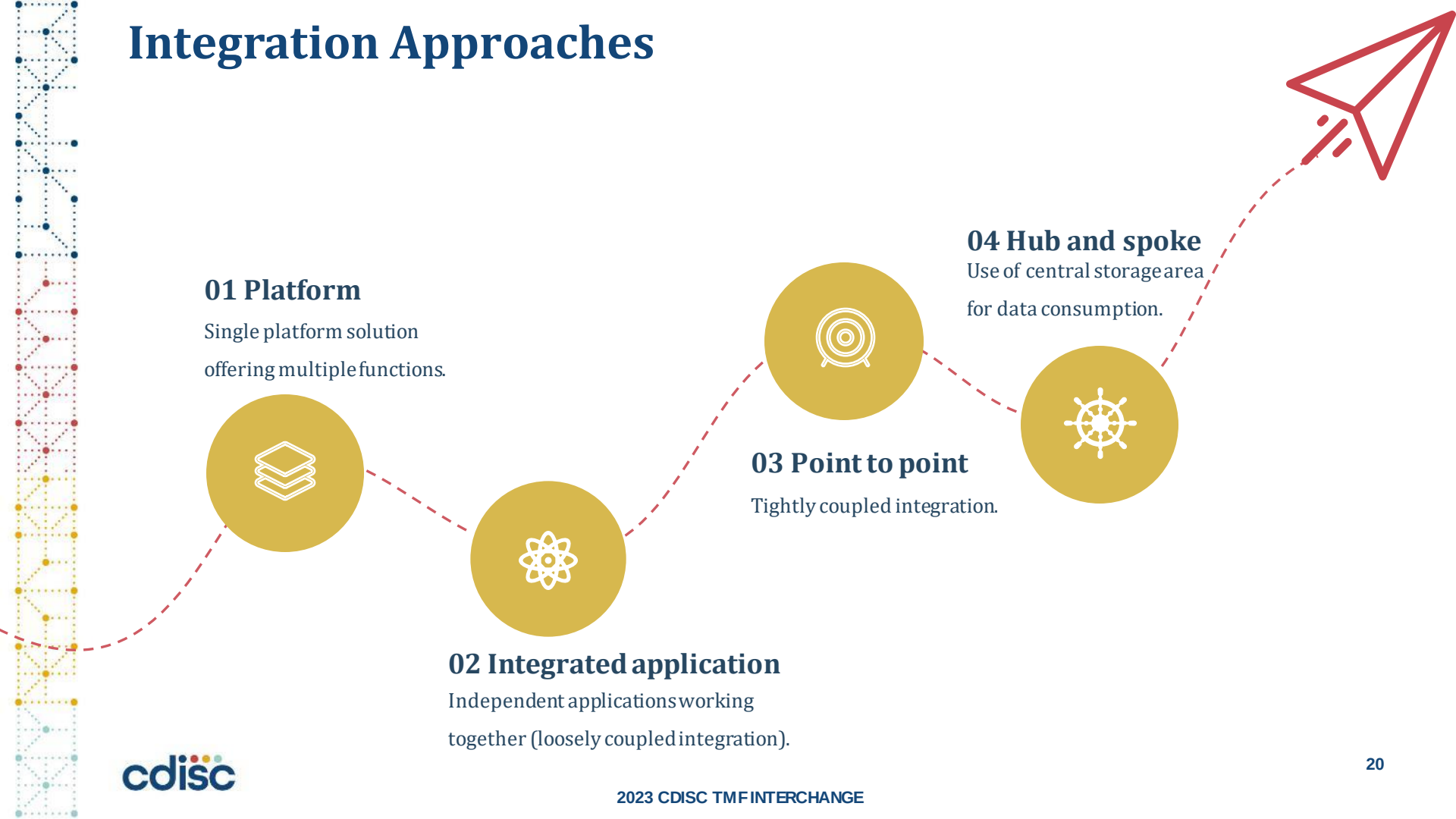
Assemble the data

Harvest new business insights using integrated system data from within and outside the organization.

Identify the option

Identify the suitable approach depending on data scope (availability and data integrity), cost and flexibility.

Integration Approaches



01 Platform

Single platform solution offering multiple functions.

02 Integrated application

Independent applications working together (loosely coupled integration).

03 Point to point

Tightly coupled integration.

04 Hub and spoke

Use of central storage area for data consumption.

Case Study

eTMF – CTMS Intersects

1. Trial Information

Product, Protocol Number, Protocol Title, Phase, Type.

2. Countries

Where the study will be conducted

3. Sites

Clinical sites that will participate and the principal investigators / sub-investigators / site staff who will participate at each site.

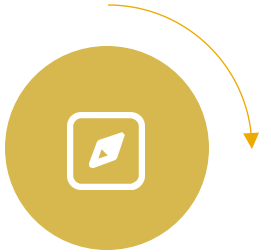
4. Laboratories and vendors

Third parties supporting the study.

5. Milestones

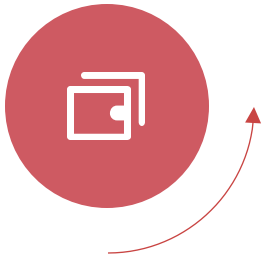
Pivotal events defined for the study, country and site.

Integration Scenario



New Study - Study Startup

Prepare eTMF with basic information needed to provision the study (IP, protocol # etc.).
Reduce manual data entry / eliminate duplicate work.



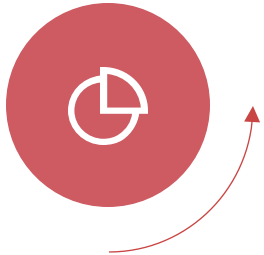
Mid-Trial Updates – Study Conduct

New sites indicates new sets of documents against site milestones.

New Investigator requires new 1572, CV etc..

Mid-Trial Updates – Monitoring

Approved visit reports, confirmation letters and follow-up letters are automatically filed in eTMF.



CTMS Status Updates

Automatically update CTMS site / country / study status based on TMF milestone completion

Lessons Learned

Lessons Learned

01 – Integration Approach

Architecture, phased vs. big bang, full data-set vs. pilot

02 – Data Quality

How clean is the data is and what is the adoption of MDM / RDM by individual systems

03 – Data Mapping

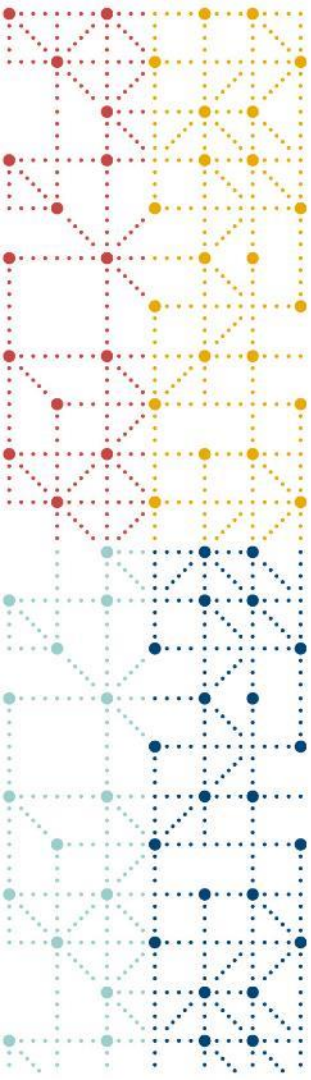
Review data mapping for accuracy

04 – Resource Availability

Are all key resources identified and available.

Tips for successful integration

1. Define **Strategy**
2. Have **Project Team Alignment** – scope, schedule, data
3. Ensure key **resource availability**
4. Include multiple rounds of **validation**
5. Focus and review **process and technology** together
6. **Communicate** and **Engage**



Conclusion

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Data is the most critical asset to clinical trial.

Data standardization preserves data quality and ensure that the information is reliable and accurate.

Integration helps clinical systems to communicate, exchange data, and use the information that has been exchanged.

Data Standardization and **Integration** ensures that the information exchange is meaningful.

Turn Data Chaos into Data Intelligence

Thank You!