



Empowering Clinical Trial Decisions with Data-Driven Management (DDDM)

Moving from Gut Instincts to
Evidence-Based Decisions

A i2e Consulting White Paper



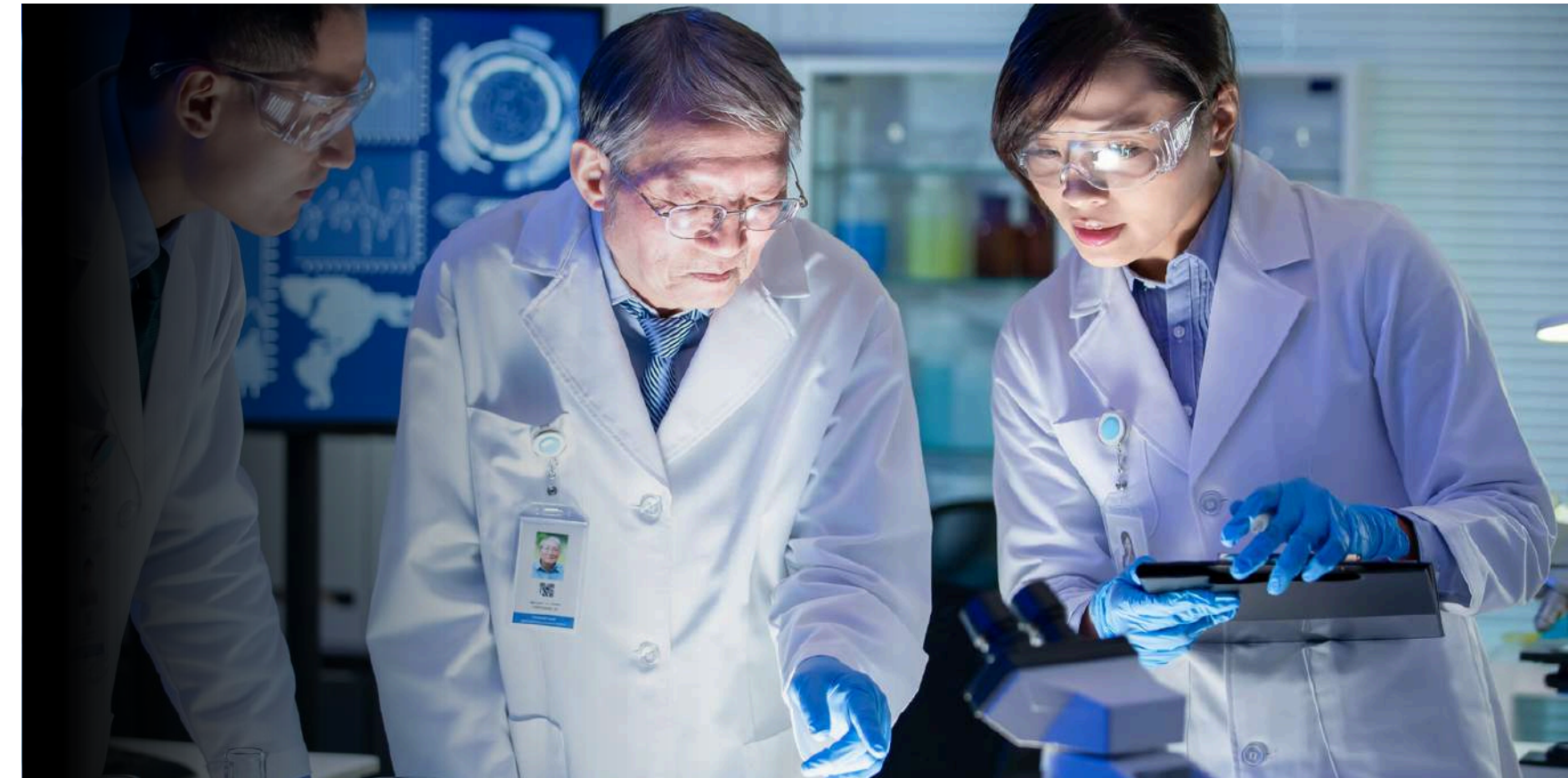
Introduction

This white paper by i2e Consulting illuminates the transformative potential of Data-Driven Decision Management (DDDM) in clinical trials. DDDM serves as a beacon, guiding stakeholders from intuition-based decisions to evidence-driven strategies.

The paper underscores the pivotal role of data quality in DDDM, advocating for meticulous data collection practices to ensure accuracy and completeness. It delves into best practices for data engineering, highlighting the importance of distilling vast datasets into actionable insights using advanced analytics and visualization tools.

Furthermore, the paper addresses the imperative of fostering a culture of change management to facilitate the seamless adoption of DDDM. Through training, communication, and technology adoption, organizations can optimize decision-making processes and enhance operational efficiency in clinical trials.

In essence, this white paper offers a pragmatic roadmap for organizations seeking to unlock the transformative power of data in driving successful clinical trial outcomes.



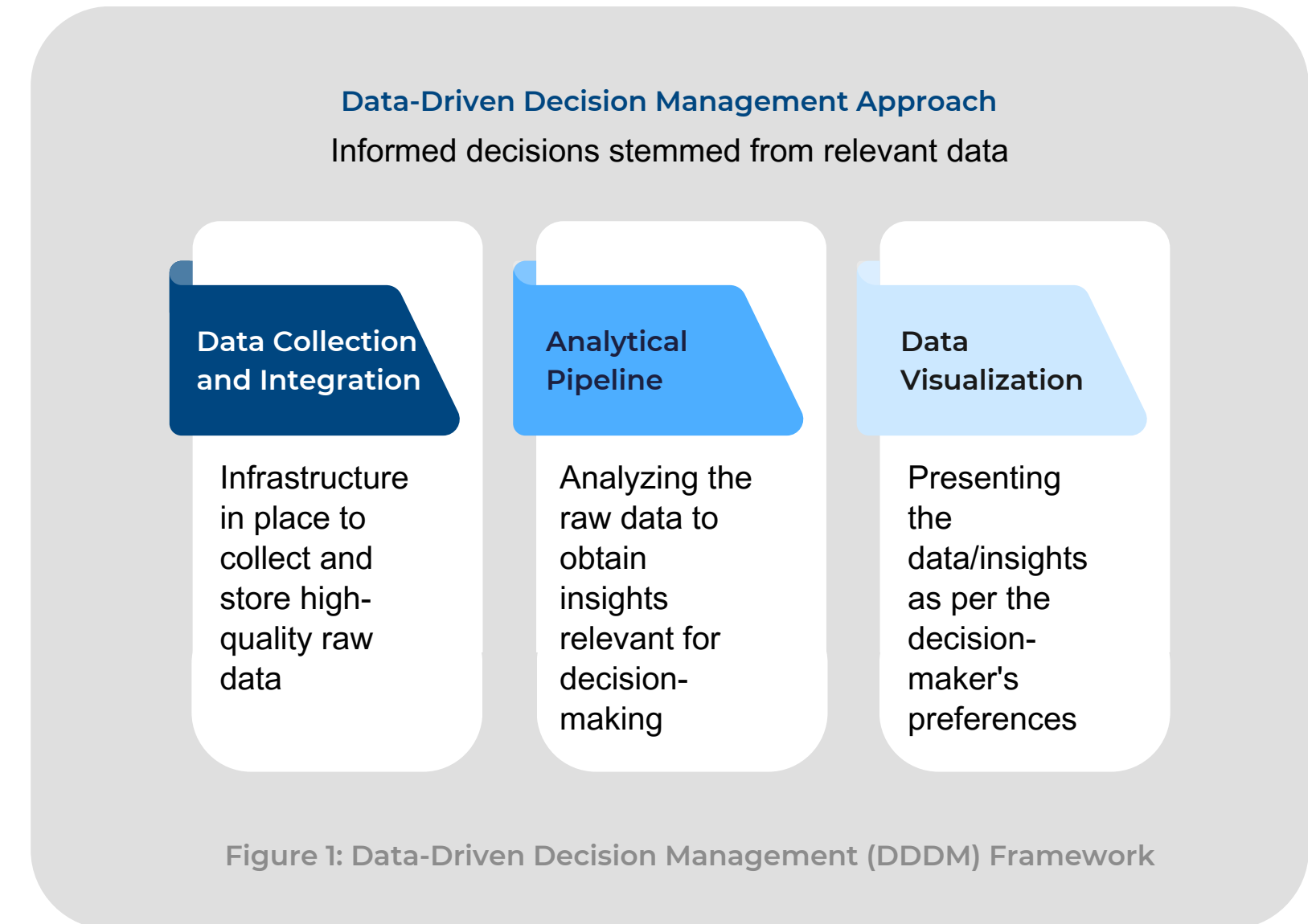
Data serves as the storyteller, weaving narratives of insight and foresight for decision-makers.

Understanding the language of data is not merely deciphering numbers; it is embracing the unfolding saga that guides pharmaceutical leaders in shaping a future of innovation, efficiency, and informed choices.

One such approach towards understanding the story behind data is Data-Driven Decision Management (DDDM)-it is a framework where business decision-making relies on the analysis of relevant data to guide strategic choices.

In the clinical trial setup DDDM can play a critical role in improving operational efficiency, reducing risks, and enhancing overall decision-making processes. For example, Key Performance Indicators(KPIs) can help pinpoint the most effective recruitment channel among several, thus enabling the optimization of Clinical Development and Operations dollars. Many organizations are already embracing the DDDM approach. A MIT study on data-driven decision making in action reveals that greater usage of data-driven decision making resulted in a 3% increase in productivity (1).

If you have not yet embraced DDDM in your organization or are struggling with operational aspects to achieve data nirvana, then don't worry- a systematic approach can move your organization into the future. The simple framework in Figure 1 will help you get started.



This whitepaper will help you navigate technological aspects at each stage in the DDDM process and address some of the common challenges along the way.

Data quality matters: How to make sure you are collecting high quality raw data.



The first step in moving towards DDDM is collecting high-quality raw data. In the pharmaceutical industry, especially in the context of clinical trials, meticulous data collection is crucial for decision-making and regulatory compliance.

What makes data high quality? The data should be accurate, timely, complete, and actionable. Additionally, it must be well defined, easily identifiable, accessible, and compatible across data systems, so that it can be used by multiple departments.

Organizations will be at different maturity levels depending on their data infrastructure and the methods they employ in collecting raw data.

Companies with low data infrastructure maturity face challenges with data quality and completeness. Without technology enabling automated data collection, manual data collection methods would be required. The problem with manual data collection is the risk of poor data quality which may result in subpar decision making. For example, in manual data collection methods where the healthcare professionals fill out paper forms to record study related data, the chance of error is both substantial and the method is time-consuming. The risk of poor data quality potentially drives nonoptimal investment decisions.

A few best practices which can ensure collection of high-quality data during clinical trials are:

- Have a clear data quality management plan in place at the start of the trial to monitor quality, prevent and address issues.
- Build in quality checks, like having a separate monitor from the sponsor to regularly audit data collection processes at sites, help catch issues early.
- Use eCRFs (electronic case report forms) and centralized databases rather than paper forms when feasible. Improves accuracy over manual data entry and allows real-time quality checks as data is entered.
- Automate data collection from devices like wearables whenever possible. This helps minimize the chance of human data transcription errors.
- Implement rigorous data management procedures around secure data transfer, storage, coding, query management, change control, etc. Follow best practices for clinical data management.
- Control access to data collection tools and databases, with editing rights granted only to trained staff. Log all changes.
- Perform statistical monitoring of incoming trial data to catch anomalies which can help identify poor quality data or fraud.



On the other hand, organizations with mature data infrastructures can face challenges in data management. These companies may have high quality data for accurate decision-making. However, the data would be enormous and spread across multiple locations. Finding the right data could be like finding a needle in a haystack. Some of the unique challenges they face are:

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Data Volume and Dispersion

The sheer volume of data spread across disparate locations can make finding relevant information akin to searching for a needle in a haystack.



Limited Discoverability

Complex data architectures and inconsistent metadata management hinder efficient data discovery and utilization.



Resource Constraints

Manually sifting through massive datasets is time-consuming and resource-intensive, impacting research and analysis efficiency.

These organizations will then have to invest in streamlining data management and embracing novel technologies like Artificial Intelligence (AI), Machine Learning (ML) and Natural Language Processing (NLP) to efficiently isolate the right data at the right time.

Fortunately, several best practices can help organizations overcome these challenges and unlock the full potential of their data riches.

Metadata Management	Implement a robust metadata management system to document data definitions, sources, and transformations. This enables clear interpretation and traceability.
Version Control	Maintain clear version control for all data updates and modifications. This ensures transparency and prevents accidental overwrites.
Data Cleaning and Error Resolution	Establish systematic processes for data cleaning and error resolution, addressing missing values, inconsistencies, and outliers.
Archiving and Access Control	Implement secure archiving practices for long-term data storage and ensure controlled access based on user roles and permissions.
Define Clear Objectives	Articulate specific goals for data analysis, aligning with research questions and development needs.
Advanced Analytics	Leverage advanced analytics tools, including machine learning and AI, to identify hidden patterns, predict outcomes, and personalize therapies.
Collaboration and Sharing	Foster a culture of data sharing within the organization and consider collaborative research partnerships to maximize insights.
Visualization and Communication	Translate complex data findings into clear and compelling visualizations and reports for decision-makers.
Data Governance	Establish ethical and legal frameworks for data utilization, ensuring patient privacy and responsible research practices.



Additional tips

Invest in Training

Provide ongoing training to researchers and analysts on data management practices, analysis techniques, and ethical considerations.

Stay Updated

Keep abreast of evolving regulatory requirements and technological advancements in clinical data management.

Consider Cloud Solutions

Explore cloud-based data storage and computing solutions for scalability, security, and collaboration benefits.

Partner with Experts

Collaborate with data scientists, clinical informaticians, and regulatory experts to optimize data utilization and navigate technical challenges.

Collecting high-quality raw data at the clinical trial site.



Real-world scenario

The first step in implementing DDDM is ensuring high-quality data is collected from all patients participating in the study across all clinical study sites. This requires extensive paperwork at each trial visit covering quality of life, symptom reporting, and medication history. In the case of manual data collection methods, there may be a high chance of missing and inconsistent data.

The amount of data that must be reviewed and evaluated to achieve high-quality data can be daunting, especially when multiple study sites are involved. This is where a pragmatic approach to obtain clean patient data becomes critical.



Solution

To address data quality issues, a generative AI chatbot can guide patients through their questionnaire at each visit. Furthermore, the chatbot engages patients in natural conversation via a mobile tablet app, asking verbally about symptoms, ability to do daily activities, and medication intake. Novel technologies such as Natural Language Processing (NLP) can help the chatbot tailor questions based on patient responses, only asking relevant follow-ups to get a complete picture within 5-7 minutes.

Researchers can also continuously improve the chatbot's question and answer library using Machine Learning (ML) based on site researcher feedback. The chatbot stores structured symptoms and quality of life data directly in the trial's clinical data management system for real-time data checks and analysis.



Outcomes

Use of the chatbot for patient questionnaires decreases data errors. Missing data can be reduced too through improved engagement and the chatbot's ability to ask clarifying questions when information was vague, incomplete, or contradictory. The data aggregated within the tool would provide Clinical Data Management teams with the data they need to extract actionable insights.

Data engineering: How to make sure your data tells the right story.

Once the process to obtain high-quality data is in place, the next step towards DDDM is to distill the data for effective analysis. The data distillation process can be complex or simple based on the stakeholder's requirement. However, most commonly the data distillation process involves applying structure to unstructured data and filtering out irrelevant data elements.

In our previous patient recruitment example, to ensure accurate budget allocations, the VP of clinical operations needs to analyze KPIs such as conversion rates, cost per acquisition, reach and engagement, and quality of patients for each channel. The KPI data collected from each channel needs to be structured to identify and compare the performance of other patient recruitment channels.



Distilling data for effective analysis of patient recruitment channels.



Real-world scenario

A crucial step in taking optimal data-driven decisions is to initiate a comprehensive analysis of the existing data. The insights from this analysis will help optimize resource allocation and cost utilization, ultimately resulting in heightened clinical trial performance and increased success rates.

To make accurate marketing allocations, the sponsor may want to identify recruitment channels that were the most successful in-patient enrollments. Additionally, the sponsor management might want a high-level view of the overall performance of all the patient recruitment channels or identify trends in channel performances

The following are necessary to achieve data-driven decisions (DDDM)

- 1 Establishing clear measuring metrics
- 2 Consolidating these metrics and insights from the collected data
- 3 Furnishing the decision-makers with an integrated platform
- 4 A centralized reporting system for comprehensive reports

Owing to the huge amount of data pouring in from various clinical sites, comprehensive analysis to bring out insights can be daunting. This is where an expert technological partner can help formulate a pragmatic approach to turn data into actionable insights.



Solution

The challenge lies in integrating data sources and reconciling diverse standards employed by various marketing channels to streamline the data integration process. Once the data integration is done, seamless Extract, Transform, and Load (ETL) workflows need to be established to facilitate the cleansing and transformation of data.

Next step is implementing advanced algorithms to extract the KPIs pertaining to the metrics defined by the stakeholders. Advanced analytics can also be leveraged to forecast trends and identify potential risks, adding a layer of strategic insight.



Outcomes

The implemented solution will facilitate data-driven decision-making by generating actionable insights derived from the high-quality data. The sponsors can drill down to manageable subsets to understand channel performance. For example, the aggregate data can be filtered and analyzed to understand why a certain marketing channel outperformed the rest.

Data visualization: Presenting the story through visuals for easy stakeholder consumption.

The final step in the DDDM process is presenting the insights collected from the high-quality data for optimal interpretation by the stakeholders. Data visualization begins with identifying the ideal mechanism to present the data. However, the type of data being presented and the audience consuming the data are both critical components for selecting the best mechanism for presentation.

For presenting data to optimize the marketing budget in clinical trial patient recruitment, an in-depth approach for presenting the data might be the optimal choice. A centralized view of the performance of all the channels with drill down capabilities to understand the reasons behind it can help the decision makers make an informed decision. Beyond addressing major Key Performance Indicators (KPIs), creating visuals that forecast trends and identify potential risks can add a layer of strategic insight.



Presenting data for optimal interpretation of the patient recruitment channels.



Real-world scenario

When it comes to budget optimizations in patient recruitment channels, stakeholders might need the data presented in three ways.

Return on Investment (ROI)

It helps decision-makers understand the efficiency of different recruitment channels in generating value for the trial.

Conversion rates by channels

Conversion rates offer insights into the efficiency of each recruitment channel, indicating which channels are most successful in turning potential participants into screened candidates.

Patient enrollment rates

This metric is vital for evaluating the overall effectiveness of the recruitment strategy in attracting and retaining eligible participants.



Solution

There is a need for a robust data visualization framework which can provide visualizations based on the aggregated data. The framework should be flexible enough to update the visuals with the creation of each new aggregated data set.

Advanced analytics visuals can be created that forecast trends and identify potential risks. This will lead to enhanced risk management by identifying and highlighting potential risks, enabling proactive measures to mitigate adverse impacts on project outcomes.

Operations managers can use the dashboards for identifying risks and trends and devise plans to mitigate them, whereas management teams can access executive-level dashboards to stay up to date with overall progress and support decisions around resource optimization.



Outcomes

A centralized reporting solution can seamlessly integrate data from multiple sources, providing stakeholders with a unified and coherent platform for informed decision-making and strategic planning.

Change management while creating a DDDM culture.

Implementing DDDM culture is straightforward and involves following the below steps meticulously:

Incorporate the data infrastructure needed to obtain high-quality raw data.

Build appropriate analytical capabilities to convert the data to actionable insights.

Present the data in a visual format for optimal interpretation.

The framework may seem simple, but the implementation requires a sequential change management approach to foster an effective DDDM culture. The first step in change management starts with training the stakeholders in making decisions based on data and being consistent with it. Once the department starts to operate outside the framework, and takes decisions based on 'gut feeling', the purpose of DDDM will be lost.

Initially, there may be resistance to adopting DDDM culture, as stakeholders would require time and training in processing the insights and taking decisions out of it.

Here are a few aspects that might help in successful change management.

- Begin by acknowledging the specific challenges decision-makers face in clinical trials, such as the traditionally conservative nature of the industry, concerns about data security, and the need for precision in decision-making.
- Develop a compelling narrative around the necessity of a data-based decision management culture. Address pain points related to prolonged trial durations, high costs, and the potential for data silos hindering comprehensive decision-making.
- Implement clear and consistent communication strategies. Decision-makers need to convey the vision behind the change, emphasizing how a data-driven culture will enhance efficiency, reduce risks, and ultimately lead to more successful clinical trials.
- Recognize the importance of training programs for employees. Decision-makers are often concerned about the skill gap and the potential resistance from teams accustomed to traditional methods. Addressing this concern helps in a smoother transition.
- Provide detailed insights into the technologies that will be adopted and their benefits. Decision-makers in the life sciences industry may face apprehensions about the compatibility, security, and reliability of new technologies such as analytics and cloud solutions.
- Establish a robust feedback mechanism. Decision-makers should emphasize the importance of continuous improvement and be receptive to feedback from all levels of the organization. This addresses concerns about potential challenges and allows for timely adjustments.
- Clearly define metrics for success and regularly evaluate progress. Decision-makers should focus on tangible outcomes related to improved decision-making, reduced trial durations, and enhanced overall efficiency in clinical trials.



Conclusion



Implementing the DDDM framework will require significant investment of time and resources. However, the returns outweigh the investment, as DDDM helps an organization to evolve and begin to solve problems based on data-generated knowledge.

i2e consulting carries over 14 years of experience in helping global pharma companies implement the DDDM framework. Our data management experts understand the nature of clinical trials data and are well versed in developing an analytical pipeline that is a best fit for your business requirements.

We provide end-to-end services to establish and embrace the DDDM culture. Our experts are technology agnostic and are flexible to work with any unique business requirements.

References

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