

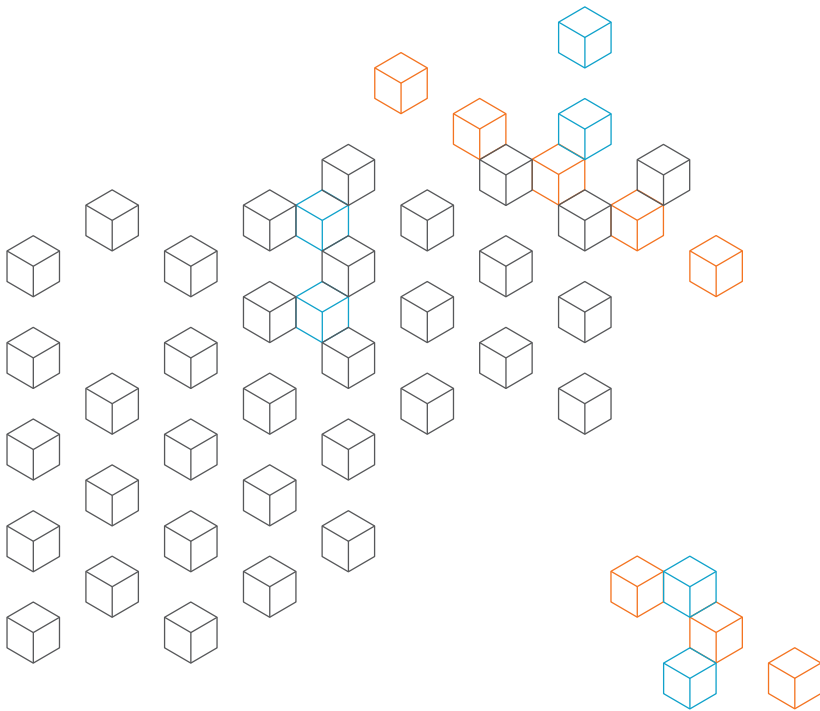
THE ROADMAP TO DIGITAL TRANSFORMATION SERIES

Part 1: The Case for a Clinical Data Strategy



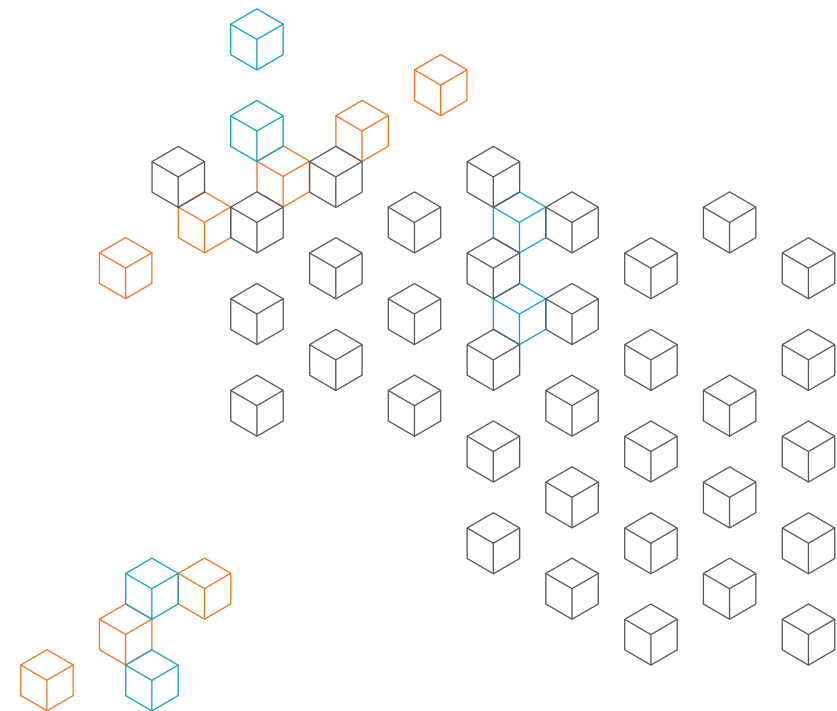
eClinical
Solutions

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Data from clinical trials is extremely valuable but often underutilized. This is typically the result of insufficient planning. Industry experts are frustrated knowing that stakeholders do not have sufficient access to their data, thus losing tremendous value since the data is not being fully leveraged; and regret that their organizations are not set up to take full advantage of the data so painstakingly acquired.

In today's environment, more data than ever is being created from an expanding set of sources spanning from wearables to genomics. Many life sciences companies are looking for ways to transform their approach to become data driven organizations with Digital Health initiatives. This makes the challenge of maximizing value from data even more critical. To do so requires an organizational approach and vision around data strategy.



One way to get everyone thinking in the proper terms when embarking on a clinical data strategy initiative is to ask each stakeholder:

If you could learn one thing from the clinical data that would help you do your job better, what would it be?

By answering this question, stakeholders are forced to think about what decisions they need to make or improve upon, what information is needed to support those decisions, and therefore what data is needed to be able to derive this information.

The implementation of the data strategy will eventually feed into a broader digital strategy. Placing the data strategy first avoids the tendency to view a digital health initiative as an IT project. Emphasizing the data strategy ties directly into the business strategy, which relies on data to make informed decisions — commonly referred to as developing a data driven organization.

The data required to make informed decisions will vary by business unit. Focusing on the data strategy first allows each business unit to independently assess how they can best consume the data of interest to them.

Consider the case of an R&D organization. Clearly Research and Development have some data of common value, but the majority of the data is relevant only to an individual unit. For example, compound library and sample management systems are critical to Research, but of no interest to Development. Likewise, clinical trial management systems (CTMS) and electronic data capture (EDC) systems are critical to Development and of no interest for Research. Yet within both Research and Development there are subunits that have their own specialized niches and varying degrees of overlapping data access needs. Therefore, it makes sense to view the entire organization's digital strategy as a network of data hubs.

Data strategy is focused on what data is needed and how it should be presented to the data consumers.

Digital strategy is focused on the tools and techniques to achieve these goals.

Each hub is focused on the data needs of its unique user base, yet ties into the broader digital strategy for sharing relevant data of value to other units. As each unit uses their data locally, resultant summarized data or a data subset can be integrated into other data hubs in the network.

To define the needs for each hub, each business unit must define their data strategy.

Data Strategy Guiding Principles

While developing a data strategy, it is useful to keep the following guiding principles in mind:

- Start with the end in mind
- Ensure all users can derive value
- Plan to share data
- Leverage standards and metadata management

Start with the end in mind. Cascade down from the end to the beginning:

- What is the organization's business strategy?
- What are this business unit's goals in alignment with the business strategy?
- What decisions need to be made in alignment with those goals?
- What information is needed to support making well-informed decisions?
 - What data is needed to provide the information?
 - How is data quality assured?
 - How is data integrity assured?
 - How timely must the data be?
 - How is data timeliness assured?

A technology infrastructure isn't worth anything if users cannot derive value:

- Data storage and loading must be automated and scalable for easy accessibility.
- Data must be summarized and presented to users so that they may easily consume and understand it in context.
- Must deploy solutions based on a modern data strategy with an ability to scale with evolving industry needs.
- Solutions must provide immediate and incremental value to all users, or they won't be used.

Beware of solutions that expect one group of upstream users to input data without adequate value to make their efforts worthwhile. While downstream users may reap tremendous value, human nature will result in insufficient input and the value of the solution will be lost.

Plan to share data:

- Consider what data may be generally available and what data must be under stricter access control.
- Define a data governance framework so that data can easily be managed, accessed and protected.

Leverage standards and metadata management to:

- Assure mutual understanding
- Establish and maintain consistency
- Ensure interoperability and reusability

For Clinical Development, a table is presented on pages 16–17 describing how relevant questions for defining a data strategy relate to the digital strategy, as well as associated clinical data strategy considerations.

Beware of solutions that expect one group of upstream users to input data without adequate value to make their efforts worthwhile. While downstream users may reap tremendous value, human nature will result in insufficient input and the value of the solution will be lost.

Elements of a Clinical Data Strategy

In order for the data to serve the various organizational needs, it must have sufficient breadth, quantity, quality, and timeliness.

Yet no matter how well the data meets these criteria, if it is not accessible it will lose its value. A prerequisite for sufficiently meeting these needs is automation. Automation is key for acquiring the data in a timely fashion, for transforming the data into a digestible format, and providing the transformed data for immediate use. These key elements for developing a clinical data strategy are described below.

Sufficient Breadth of data refers to assuring that all relevant data is available. This includes, but is not limited to:

- Case report form data from an electronic data capture (EDC) system,
- Laboratory test results,
- Patient or care-giver reports from devices and apps such as electronic patient reported outcomes (ePRO) and clinical outcome assessments (COA),
- Non-CRF data and expert interpretations such as from reading images such as X-Rays or echocardiograms,
- Trial operations data such as from a clinical trial management system (CTMS)
- Reference data such as:
 - Normal and alert ranges for laboratory tests
 - Normal and alert ranges for vital sign measurements
 - Conversion factors to transform nonstandard units of measure into a standard unit
- Real World Evidence data:
 - Health Economics related data
 - Claims data
 - Procedure cost data
 - Electronic Health Records such clinical data from site electronic health record systems
 - Compound class related data:
 - Adverse events prevalence
 - Known drug interactions

Automation is key for acquiring the data in a timely fashion, for transforming the data into a digestible format, and providing the transformed data for immediate use.

Sufficient Quantity of data refers to having all the available data from all relevant sources, including all the data to date for a given trial as well as data from other relevant trials for the same investigational product and/or for the same indication.

Sufficient Quality means that not only should the data from the individual data sources be clean, but that the data must be consistent across source systems. Despite best intentions and efforts to clean the data in the individual sources, new issues will be found as the data is combined and curated from different perspectives. Therefore, users must have a way to raise and address any issues that become apparent during this process.

Sufficient Timeliness has two important components:

- Making the data available in as close to real time as possible. This implies seamless integrations to source data systems to receive data.
- Removing barriers and delays associated with creating reports, listings, or graphs to summarize the data. This implies providing self-service mechanisms so users do not have to rely on submitting requests and waiting for someone else to generate a report for them.

Sufficient Accessibility refers to:

- Assuring that users with the right to know can directly view all data of interest.
- Assuring that users can view the data in a variety of summary presentations, facilitating interpretation of the data.
- Assuring that users can easily navigate through the data to follow data leads wherever they go. This may involve drilling down from summaries into individual subject details; or pursuing leads across data domains, and even across studies.

Automation refers to:

- Integrated data feeds from data source systems that automatically bring in new/updated data per a defined time schedule and/or event trigger.
- Tools to compare incoming data metadata to defined standards.
- Tools to automate transformation to the desired analysis-ready dataset.
- Tools to automate presentation of summarized and graphical representations of data.
- Automatic incorporation of new/updated data into summarizations and visualizations.

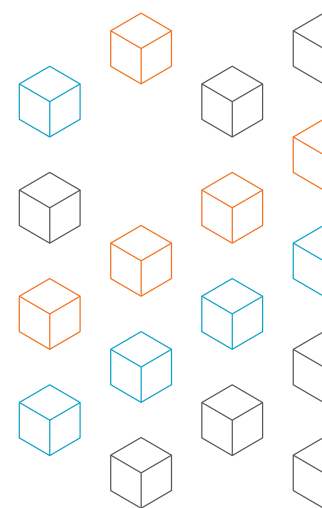
Top Five Considerations for Creating a Successful Clinical Data Strategy

1. Get Executive Sponsorship:

The identification of the need to create a clinical data strategy often starts with one of the functional units within Clinical Development. Organizational differences lead to a wide variety of next steps from immediately seeking executive sponsorship to developing a comprehensive proposal to get executive sponsorship. Either way, as a cross functional endeavor, it is important to obtain executive sponsorship.

Key points that are associated with successfully gaining executive sponsorship include:

- Showing alignment between the Business Strategy and Clinical Data Strategy
- Outlining value opportunities:
 - Make better informed decisions.
 - Make Go/No-Go decisions earlier.
 - Improve decisions by bringing data together from multiple sources.
- Outlining risk reduction opportunities:
 - Identification of safety signals earlier.
 - Earlier identification of investigator site issues.
 - Demonstration that company is actively leveraging all data assets as part of fiduciary responsibility to assure subject safety.
- Moving away from a custodial approach to data and toward using data more proactively to support a data driven model.

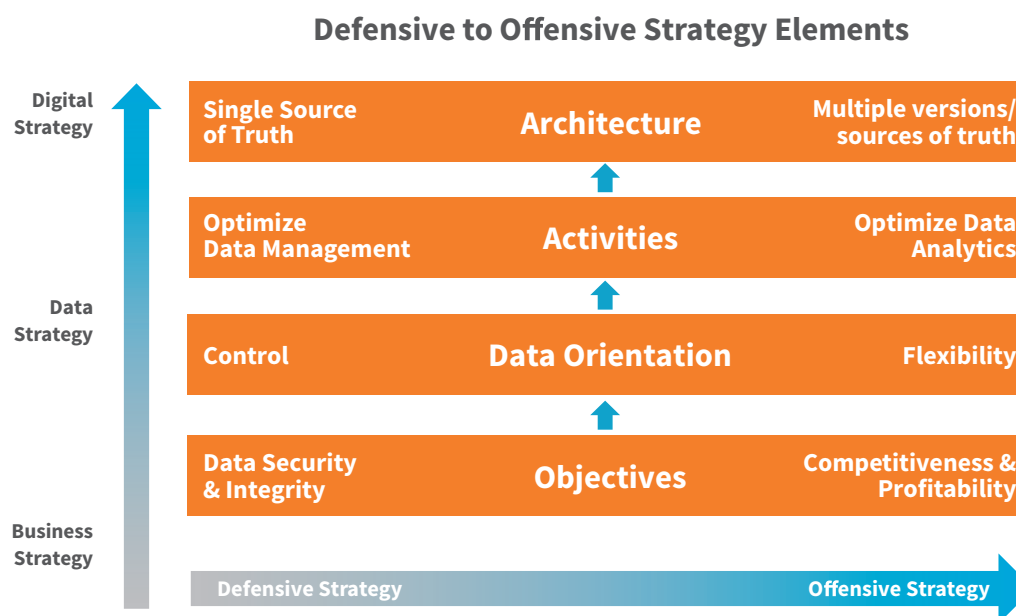


2. Define Scope & Set Objectives

The appropriate objective will vary based on the company size and stage in the life cycle of the product lines. L Dallemule and T Davenport described defensive and offensive data strategies in their HBR article “What’s Your Data Strategy?” It is tempting to jump to the conclusion that a more offensive strategy is better, but the appropriateness depends on the industry. Heavily regulated industries (such as pharmaceuticals and healthcare) place a greater emphasis on defensive measures to assure data quality and protection. Financial institutions are also heavily regulated while facing very dynamic markets; as such they seek a more balanced approach between both defensive and offensive objectives. The retail space is much less regulated and demands rapid adjustment to market changes; hence much greater emphasis is placed on offensive objectives. No industry focuses solely on one aspect or the other; it is a balance based on the nature of the business environment in which members of that industry operate.

Combining the transitions from business to data to digital strategies together with the concepts of defensive to offensive data strategies is illustrated in the accompanying diagram. None of these concepts have well-defined boundaries; they are all continuums that overlap and feed into each other.

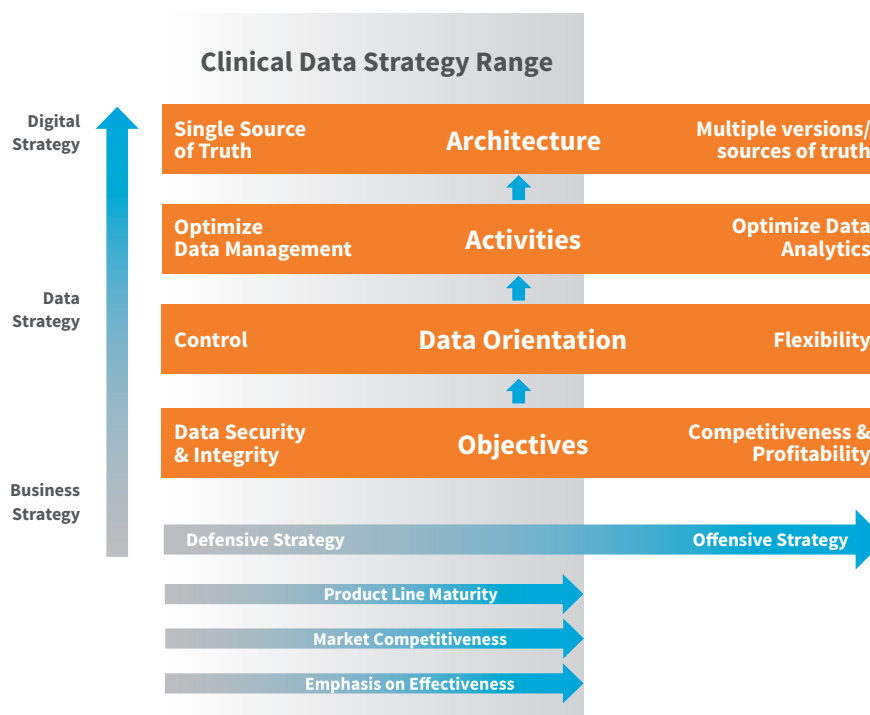
No matter what the industry is, forces in the broader business environment will be pushing everyone to move towards the offensive end. This doesn’t mean that the defensive aspects are dropped, but they become a foundation from which more offensive opportunities are sought.



2.1. Factoring in Your Portfolio

Setting the scope for the objectives of a Clinical Data Strategy must adhere to these same precepts. Previously a Clinical Data Strategy would have been pegged close to the left side of the chart on page 9. Today the position is a range shifted more towards the center. Within this range, organizations that have more mature product lines, face stiffer competition, or are start-ups looking for dramatic efficiency advantages from a data driven culture, will be further to the right within this range. More mature product lines will have a variety of factors that push for a more offensive position. These include greater volumes of data from both internal and external sources, greater variability in data sources and data types, and greater competition. As competition becomes stiffer, organizations need more data at their disposal to evaluate and react to this competition, as well as tools for making data available to support well informed decisions in a timely manner. Both the need to respond to competitive pressures and the drive to succeed as a start-up demand an emphasis on effectiveness. From a data perspective, this includes getting the right data together, provided to the right people, in the right format, and in an efficient manner.

A clinical data strategy is, by definition, a strategy. As such, it outlines a desired goal or future state. Jumping to build a comprehensive final solution with all the data and all analytics at once is a recipe for failure. A much more successful approach is to break the implementation down into near, mid, and long-term objectives. It is best to start with a well-defined set of data and use cases that exploit this data. Plan on an incremental iterative approach to improve use case support, followed by additional incremental iterative expansion of data and supported use cases.



3. Outline Data Time Horizons:

Identify what categories of data are needed for the near, mid-, and longer-term objectives. In alignment with using an iterative approach, the identified data for the mid- and longer-term objectives are more prone to revision.

For each of the defined data categories, identify:

- Source(s) of the data
- Data format(s)
- Data model(s) and mapping requirements for analytics readiness
- Data aggregation needs
- User Roles and Personas
- Use cases in which the data will be used
- Access requirements for downstream applications and tools

Common bucketing of data by time horizon for clinical data strategies:

- Near Term: clinical trial data for ongoing trials and associated common reference data
- Mid-Term: inclusion of legacy clinical trial data, trial operational data, and expansion of scope of reference data
- Longer-Term: inclusion of Real World Evidence data

4. Outline Associated Workflows

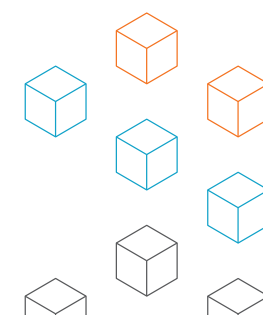
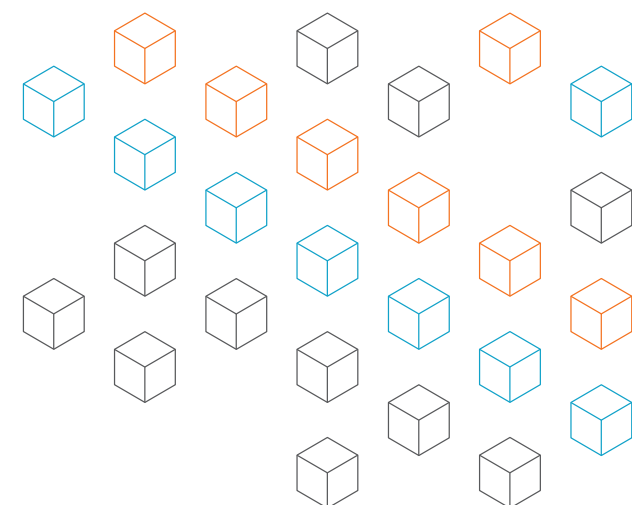
To be an effective exercise, a data strategy must consider the workflows associated with all aspects from acquiring the data through to final decisions and actions. The best way to approach this is to outline the use cases interacting with the data from inception to archive.

Useful questions to consider include:

- What are the steps (use cases) that the data goes through during the course of its life cycle? A good way to identify the steps is to think in terms of the actions that must be taken.
- Who interacts with the data at each step in its life cycle?
- What value is assured or derived at each step?
 - What is required to maximize the value?
 - What is required to maximize efficiency of deriving or assuring value at this step?
- How is the data handed off to the next step?
 - What are the prerequisites for the next step that can be facilitated here?
 - How are participants of the next step aware that the prior step has been completed?

5. Define Analytics Strategy**For each of the identified use cases, consider:**

- What action should be driven by the outcome of the use case?
- What decision is needed to drive that action?
- What information is needed to make a well-informed decision?
- What data needs to be summarized to provide that information?
- How should the data be best summarized for users to interpret it and to convey it to others?
- Preferred data presentation approach (listings, tables, dashboards, graphical visualizations)
- Interactivity needs such as drill down, tagging, setting flags, etc.
- Sharing and collaboration needs such as commenting, raising issues, etc.



Combining it ALL

Combining insights gained from the above considerations becomes the basis of documenting the data strategy to capture:

- Business unit's objectives
- Types of actions to be supported
- Types of decisions to be supported to drive those actions
- Data required to support those decisions
- Data Sources
- Data timeliness requirements
- Data presentation expectations
- Standardization approach
- User access and governance requirements
- Data retention requirements
- Timeline horizons for including different data categories



Webinar

In a recent study by the Tufts Center for the Study of Drug Design, respondents with a formalized data strategy reported less difficulty with data activities such as ingesting, integrating and analyzing data.

Find out more when Ken Getz discusses the survey results in this Feb. 26 webinar.

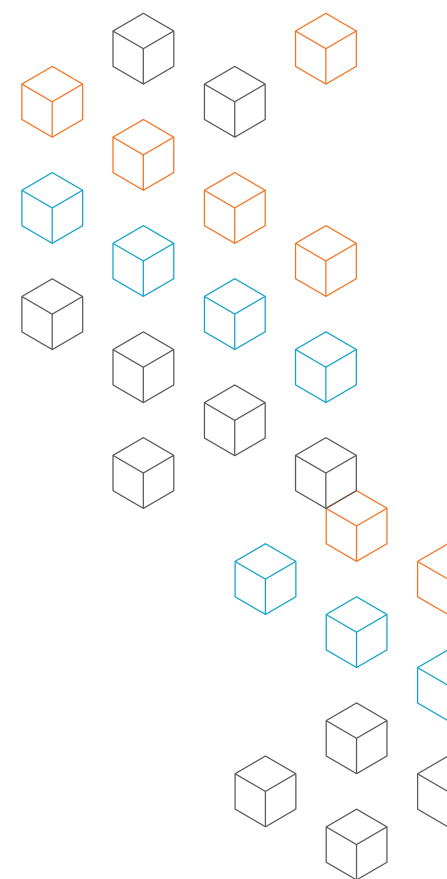
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Conclusions & Key Takeaways

As this paper has outlined, developing a data strategy is an important initiative for Life Sciences organizations in order to maximize the value of the data collected across functional areas. Organizations can prepare for a successful data strategy by keeping these five conclusions in mind.

1. Meeting the demands of clinical trials requires data with sufficient breadth, quantity, quality, timeliness, and accessibility.
2. Preparing to meet these demands is best accomplished by establishing a data strategy.
 - A. Complementary analytics and standards strategies are required for a successful data strategy implementation.
 - B. Automation is a prerequisite to sufficiently meet the data demands for supporting clinical trials.
3. A data strategy focuses on what data is needed and how it should be presented to the data consumers; a digital strategy focuses on the tools and techniques to achieve the data strategy goals.
4. To meet the needs of individual business units, each unit should independently define their unit's data strategy.
5. Clinical data requires a strong defensive data strategy as foundation as well as a complementary analytics and standards strategy. Environmental drivers are pushing towards adoption of more offensive capabilities as well.

The next paper in this series will investigate aligning the clinical data strategy with the implementation of a digital strategy and foundational platforms that drive digital data strategy. If you would like to receive the next paper in the series once published or would like more information, please email us at info@eclinicalsol.com.



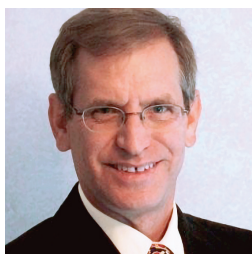
About the Authors

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Raj has spent the majority of his career supporting Clinical Data Management and Programming objectives by introducing and implementing solutions and technologies to further clinical research development.

With a unique blend of hands-on technical and data management experience, Raj works to advance the eClinical Solutions strategic vision and the delivery of cloud-based clinical solutions. Raj is responsible for the overall direction and management of the company and is passionate about bringing innovative solutions to the industry.

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A life sciences industry veteran and clinical systems expert, Rob Musterer has over 25 years of experience in clinical programming, biostatistics and data management in large pharmaceutical companies including Bayer Healthcare and Schering-Plough Pharmaceuticals. Rob most recently served as President of ER Squared, Inc., a life sciences consulting firm with an e-clinical focus. Rob began in pharma as a data manager. Seeing possibilities to improve the model, he engaged in early deployments of electronic data capture (EDC) systems and championed the change management required to adopt EDC. Rob has dedicated his career to helping the life sciences industry obtain greater time-to-value from their solutions and break from historical clinical research processes through innovation. His expertise extends far beyond EDC and includes data management services, clinical trial programming, data repositories, data visualization, clinical trial management systems (CTMS), standardization, validation and more.

For Clinical Development, the following table describes how relevant questions for defining a data strategy relate to the digital strategy as well as associated clinical data strategy considerations.

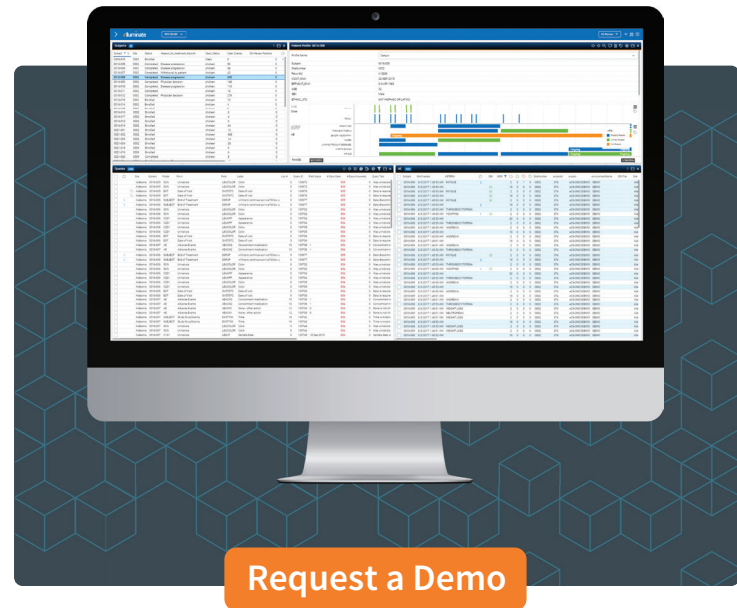
Data Strategy	Digital Strategy	Clinical Considerations
What data is needed to support decisions that need to be taken?	How will the data be brought in-house? What data is common across business units?	Clinical trial data including data captured in the CRFs and non-CRF data. Trial operational metrics. Medical terminology coding results. Health economics data.
Who needs access to the data and for what purpose?	How will access control be managed? How granular must access control management be? What tools do users need to work with the data?	Data Management: facilitate data cleaning Clinical Operations: review data Medical Reviewers: Safety and efficacy assessments Statisticians: complete data set access Safety Review Boards: assess safety Drug Safety: research serious adverse events
Have both operational data and project data needs been adequately considered?	How will operational and project data be stored?	At minimum need all clinical trial data. Advantageous to include operational data as well.
What is the life span of various data components?	How will data retention policies be created, tracked, enforced? What data archive mechanisms will be used?	Indefinite
Are there new or unconventional data sources that can be of value?	How can new data sources be integrated and brought in-house?	Prepare to accept electronic health record feeds, wearable device data, biomarker genomic data, health claims data, other health economic data, and pharmacovigilance relevant data.

Data Strategy	Digital Strategy	Clinical Considerations
How much data is needed?	What is the appropriate system architecture to support anticipated data volumes and growth?	All clinical trial data. Historically such datasets were relatively small; with growing interest in new data sources, this will dramatically increase.
What measures can be used to indicate data quality?	How can quality measures be supported through technology? How will standards across data sources and business units be defined, implemented, and maintained?	Numbers of open queries and issues, and indications of review completion.
Where is there risk to data integrity?	What security measures will be implemented to protect data in transit and at rest?	Greatest risk is in the gap between systems — need to have fully controlled secure data flow.
How timely does the data need to be?	What mechanisms will be used to automate bringing in data to meet business timeline requirements?	As close to real time as possible.
What data elements need to be combined with data from other sources?	How will databases be structured to support data integration? Will a master data management system be implemented?	Depends on trial design. Assume any data domain may potentially need to be combined with any other domain.
What types of summarizations are needed to transform the data into information?	What visualization and reporting tool functionality is required? What solutions can best meet the needs of the business units?	Variety of tables, listings, and visualizations (for example: line graphs, bar charts, heat maps, tree views).
What data transformations are required to support summarization?	What tools do users need to transform data structures?	Conform data to CDISC defined standards.

There are numerous questions related to the digital strategy not included in the above table, related to: solution architecture, security, access control, vendor qualifications, and system validation. Going beyond this, implementation planning needs to factor in change management, training, SOPs, and roll-out planning.

Learn More

The **elluminate® Clinical Data Hub** is a cloud based enterprise software platform that makes clinical data acquisition, mapping and analysis easy and intelligent for clinical teams. More than 100 life sciences companies have used the elluminate platform and software enabled services from eClinical Solutions to regain control of their clinical trial data. For more information or to request a demonstration, visit us at **www.eclinicalsol.com** or email us at **info@eclinicalsol.com**.



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