eClinical
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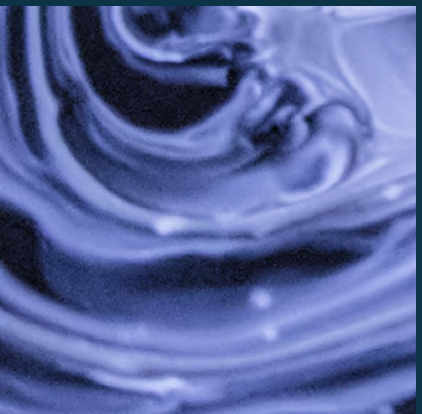
Opportunities to Accelerate Decentralized and Digital Trials

Roadmap to Digital Transformation Series **Part Two**

White Paper



What's Inside

Introduction

There are many challenges in bringing new drug therapies to market, but one of the most pressing is how life sciences organizations can rapidly harness, organize and analyze the increasing volume and variety of clinical data that are now available. This is clearly demonstrated in the fact that the amount of clinical data per trial has grown by 183 percent in the last decade.[1]

Clinical research hinges on high quality data, and the rate at which this data is expanding represents a larger trend in drug development. Life sciences companies are now managing studies that are more complex than ever before. Trials now have more than 70% of their data coming from outside of EDC systems including numerous types of labs, eCOA platforms, decentralized trial systems and numerous other clinical data sources. Adding to this complexity are the new types of data collected including longitudinal streams from wearables, along with biomarkers, omics, images and videos. There has been significant investment, enthusiasm and innovation around designing a better overall trial experience for both patients and sites in order to increase participation rates and ease of use while taking advantage of technical advances in both mobile computing and lightweight sensors.

In contrast, the process, tools and methods of "organizing" clinical data which include data ingestion, integration, standardization, review and analysis have not changed substantially over the past twenty-five years. As in many other industries, clinical development has spent more time focusing on its primary clients, patients and sites than their internal teams. Whether outsourced or insourced, every trial has teams of people responsible for setting up systems for data collection and then preparing, synthesizing, integrating, monitoring and analyzing data throughout the duration of the trial. Gaining a deeper understanding of the current state of data processing, review and insights activities and their impact on research was the goal of the Tufts-eClinical Study discussed in this paper.

The study results demonstrate the need for investment in modern technology platforms to successfully handle the influx of new data streams available in research today, as well as those coming in the future. They also demonstrate the opportunity that exists to significantly improve business outcomes with high economic impact such as decreasing cycle time metrics and increasing analytics maturity to proactively manage risk. Results also highlight the opportunity that exists today to improve and transform user experiences for all the stakeholders in the clinical development process.

[1] Getz, K, *Anticipating the Impact of the Patient Engagement Movement on Clinical Operations*, Presentation at CROWN conference, Slide #9, January 2020

Studying Clinical Data Organization & Analytics Trends

To understand the current issues that life sciences organizations face today in clinical research and the different approaches that are being used to address them, eClinical Solutions and the Tufts Center for the Study of Drug Development (Tufts CSDD) surveyed 149 individuals in senior-level data management, data sciences, biostatistics, information technology and clinical research operations roles. Titled the Tufts-eClinical Solutions Data Strategies & Transformation Study, the survey took place from October 4 to December 30, 2019.

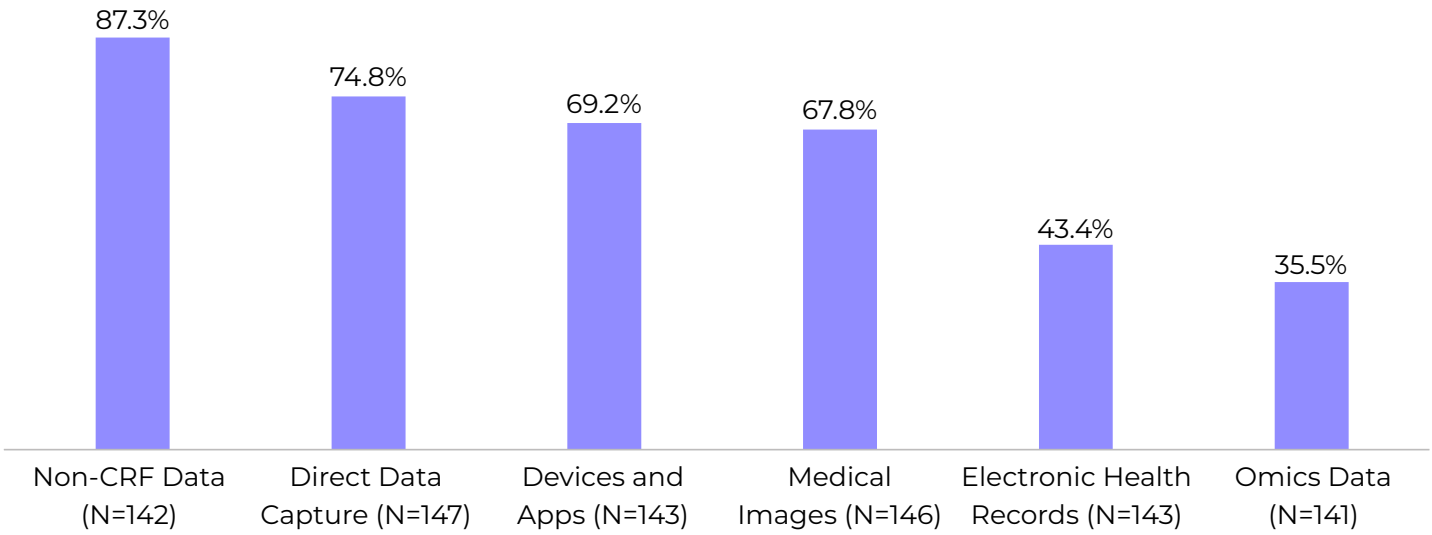
Forty-eight percent of the participants were one of several members in their organization who were responsible for clinical data, 33 percent were primarily responsible for clinical data functions and 19 percent were frequent users of clinical data systems.

Most of the respondents came from pharmaceutical (41%) and biopharmaceutical (37%) sponsors, but CROs (10%) and independent contractors (6%) also participated. The sizes of respondents' organizations ranged from small sponsors (30%), to medium sponsors (29%) and large sponsors (17%). Small sponsors were defined as those that had initiated an average of 2.9 trials yearly, while medium sponsors were those that had initiated an average of 23.8 trials yearly and large sponsors were those that had initiated an average of 112.4 trials yearly.

Challenge #1: Data Volume and Diversity Have Expanded

One of the challenges highlighted in the study was the increasing variety and volume of clinical data. For 87 percent of participants, non-CRF data is still the most common type of data being used in trials, but there are also new sources being collected. Nearly two thirds of sponsors are now using direct data capture, apps, devices and medical images in their studies, while approximately one-third of sponsors are incorporating electronic health records (43.4%) and omics data (35.5%).

Clinical Data Source Incorporation

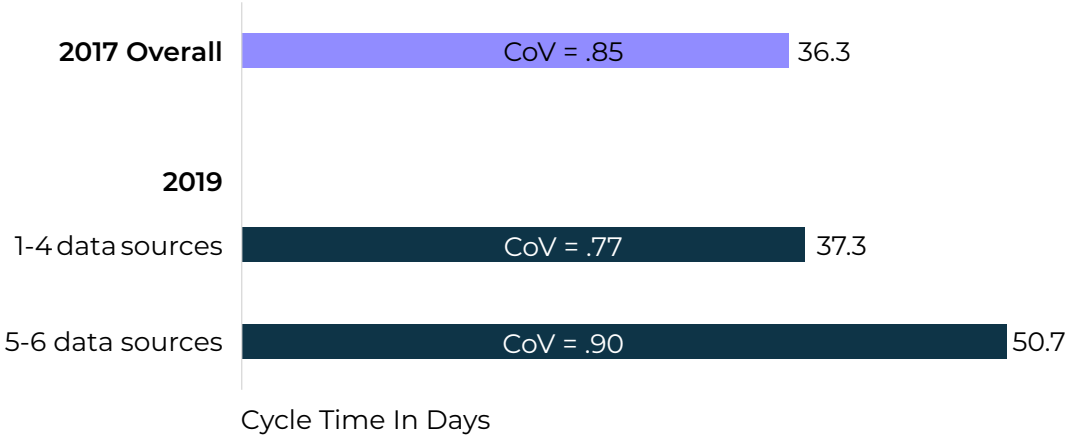


Challenge #2: Data Sources Are Causing Significant Study Delays

One of the key and surprising findings of the study is there has been a 40% increase in the Last Patient Last Visit (LPLV) to database lock cycle time metric for those sponsors using more than four data sources. In fact, those sponsors using more than four data sources in a given trial now see the LPLV to database lock cycle time metric at 50.7 days, more than 10 weeks and longer than the former cycle time metric of processing paper CRFs.

In terms of the type of data associated with these delays, more than half of the participants in the Tufts-eClinical Solutions study noted that non-CRF data was the main contributing factor.

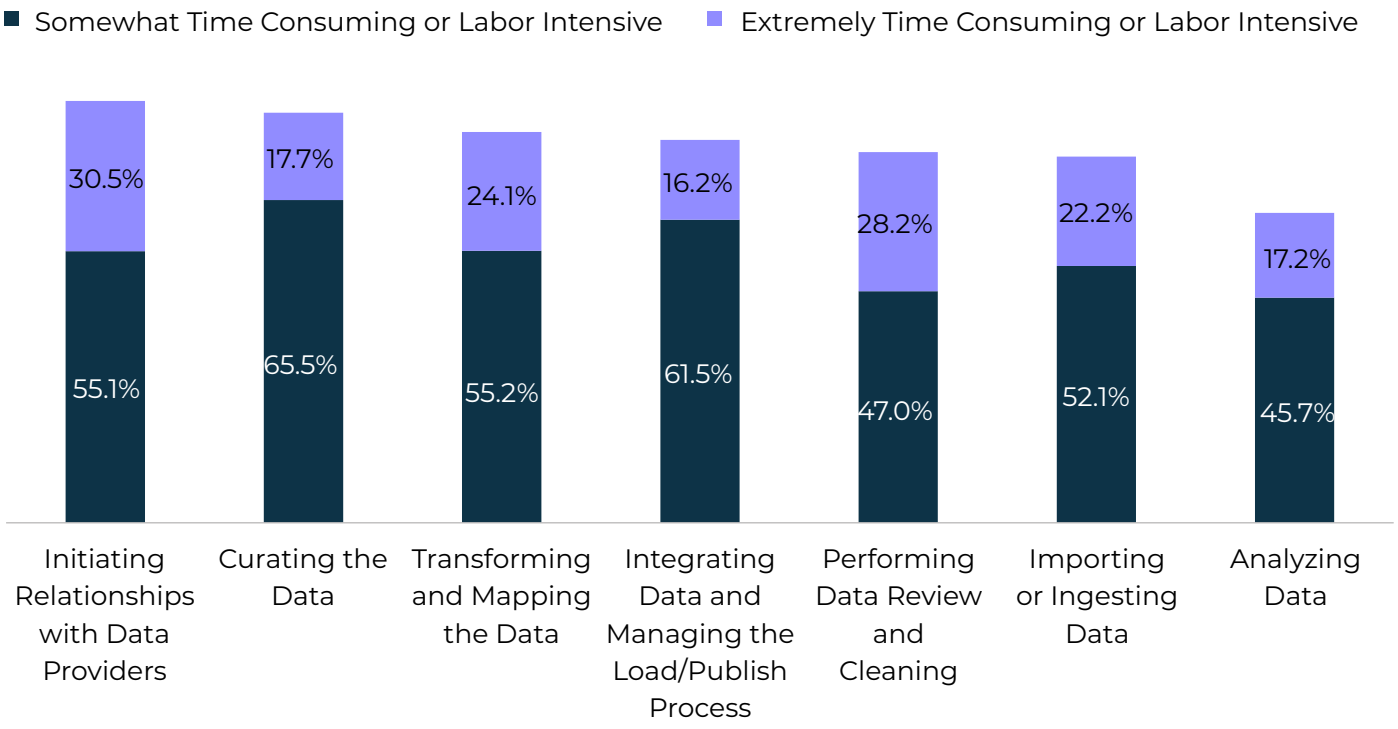
Last Patient Last Visit (LPLV) to Database Lock Cycle Times



Challenge #3: Data Management Activities Are Labor Intensive

Having richer data sets in trials has allowed sponsors to glean deeper insights in clinical studies, but the volume of information has also made data management tasks more difficult across the board. Participants in the Tufts-eClinical Solutions study indicated that all seven key data management tasks mentioned in the survey, including data cleaning, review, transformation and mapping, were either somewhat or extremely difficult.

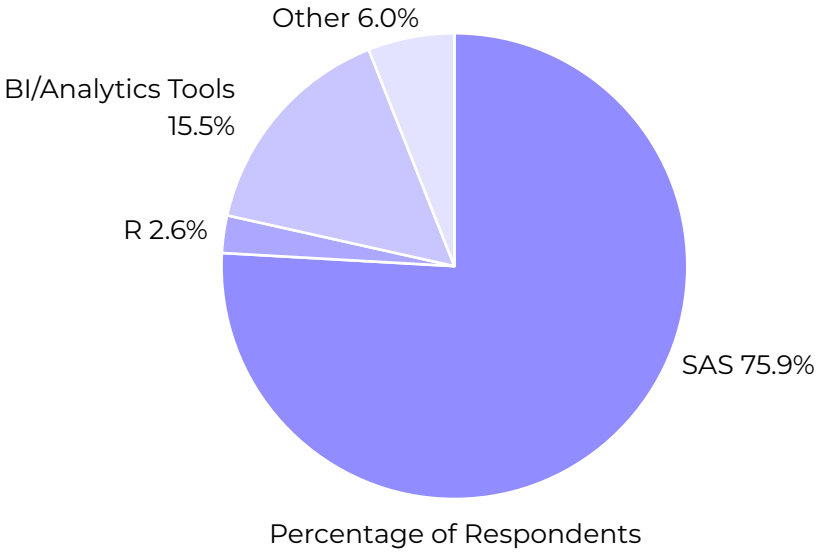
Data Management Activity Labor Intensiveness



Although data management activities have become more difficult and time-consuming and the volume and diversity of clinical data continue to grow rapidly, the tools used for data integration and analytics have not evolved to keep up with the pace of change in the data. Seventy-five percent of organizations are still converting, exploring and analyzing data with SAS as their primary tool.

Challenge #4: The Need for Tools to Centralize and Standardize Data

Primary Tool for Exploring and Analyzing Data



Data integration tools and analytics have not evolved to keep up with the pace of change in the data.

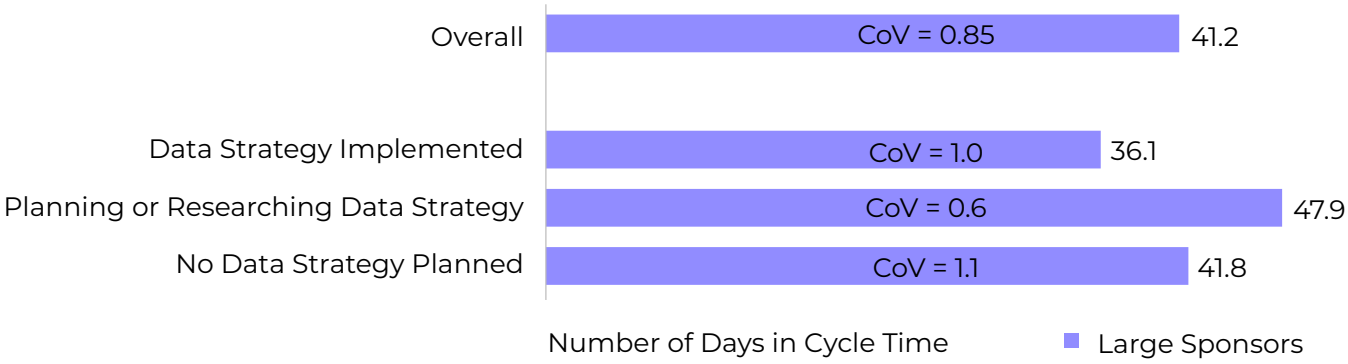
Overcoming Data Review & Management Challenges to Accelerate Digital Transformation

Drug development is evolving at a rapid pace, and this has necessitated innovations in technology and improvements to processes so sponsors can effectively manage the proliferation of data. While respondents in the Tufts-eClinical Solutions survey identified specific areas where improvements could be made, including reducing cycle times through streamlined processes, promoting patient-centered data acquisition strategies and creating better opportunities for real-world data uses, they also highlighted the following approaches that have had significant benefits to data quality, timelines and study outcomes.

Opportunity #1: Define Your Data Strategy

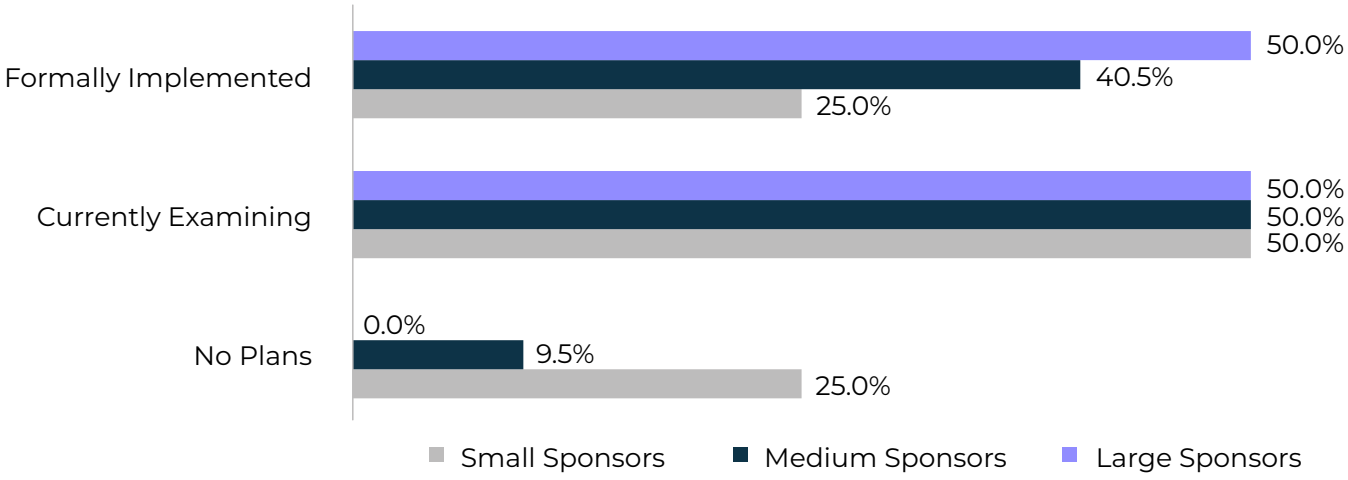
One of the most significant findings of this research was when an organization creates a data strategy that defines how data will be collected, processed and analyzed, there are significant benefits to their trials. One of those benefits is to database lock cycle times, which are reduced by an average of two weeks when sponsors implement a data strategy.

Last Patient Last Visit (LPLV) to Database Lock Cycle Time Subgroups



Only one-third of the Tufts-eClinical Solutions study participants have implemented a robust data strategy, so there are tremendous opportunities that still exist for organizations to access the benefits of executing such a strategy. Nearly half of the respondents were either in the process of considering or planning a data management initiative.

Data Strategy Implementation by Company Size



Opportunity #2: Leverage Modern Technologies to Centralize and Automate Data Activities

Organizations that are faring better than their peers are using more sophisticated tools to contend with the variety of data in their trials. The survey reveals that clinical data hubs or repositories are implemented more often than other systems, such as EDC and SAS-based infrastructure to integrate and organize data.

As the volume of data continues to increase, tools like clinical data hubs/repositories and platforms with powerful capabilities to import, transform and review data are critical in helping life sciences companies handle labor-intensive and time-consuming data management activities.

Improve data access and quality to accelerate cycle times.

Play webinar

Additionally, those organizations that had both a data strategy and had implemented a data hub or lake, rated their analytics capabilities and analytics maturity competencies as significantly higher in areas associated with analytics dashboards, predictive analytics, interactive visual exploration, augmented data discovery and with analytic content publishing and collaboration.

Solutions Used to Integrate and Organize Data

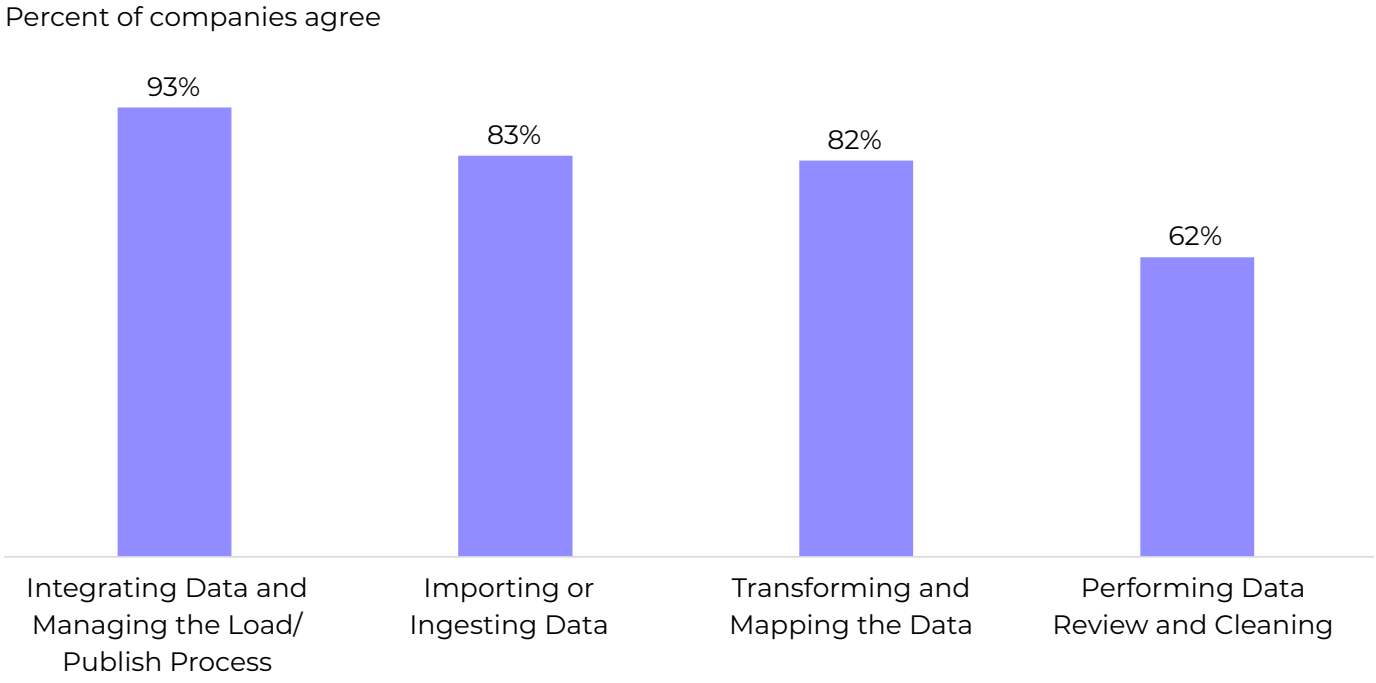
Percent of Companies	EDC	SAS Based Infrastructure	Clinical Hub/ Repository	Other
Non-CRF Data (N=116)	20.7%	46.6%	**49.1%**	8.6%
Direct Data Capture (N=108)	**50.9%**	36.1%	33.3%	5.6%
Devices and Apps (N=99)	24.2%	42.4%	**54.5%**	4.0%
Medical Images [N=95)	8.4%	27.4%	**53.7%**	23.2%
Electronic Health Records (N=79)	20.3%	31.7%	**44.3%**	16.5%
Omics Data (N=78)	3.9%	33.3%	**41.0%**	32.1%

* Multiple responses accepted

Source: Tufts CSDD-eClinical Solutions Study, 2019; N=149 companies

Currently, many data-related activities associated with clinical data management and review are manual and labor intensive. Respondents shared that most of these activities could be automated including the loading, integration and publishing process. Such automation is a key feature of modern clinical data platforms.

Leading Data Management Areas Suitable for Automation



Modern Technology Platforms and Data Centralization Accelerate Digital Transformation

As demonstrated in this study, the process of organizing and analyzing data is becoming a rate limiting step in clinical development. This is due to the challenges that come with older technology architectures which sometimes need expensive code customizations, may have reduced data processing and analytics capabilities and require high maintenance overhead. With a modern clinical data platform, these challenges can be overcome, resulting in benefits that impact organizations immediately:

- **Improved system performance:** Agile and scalable to meet shifting data volumes, the powerful capabilities built into modern clinical data platforms enable the flexibility to complete data transformation processes without interruptions to critical business functions.
- **Reduced cost and effort:** Intelligent mapping tools and standardized processes simplify data acquisition and transformation, while automated data pipelines mean the costs associated with system integrations and operational support are minimized.
- **Shorter cycle times:** With smarter, more efficient integration of diverse data sources, trial cycle times are reduced.
- **Increased productivity:** Manual processes are reduced with automated capabilities that enable self-service access for data review, query management and analysis.
- **Enhanced decision making:** Real-time access to clinical trial data and analysis translates into greater insights that inform and improve decision-making processes.
- **Faster responses to regulatory issues:** Easier access to metadata and lineage information enables quicker responses to regulatory inquiries.

Opportunity #3: Invest in Data Sciences Capabilities

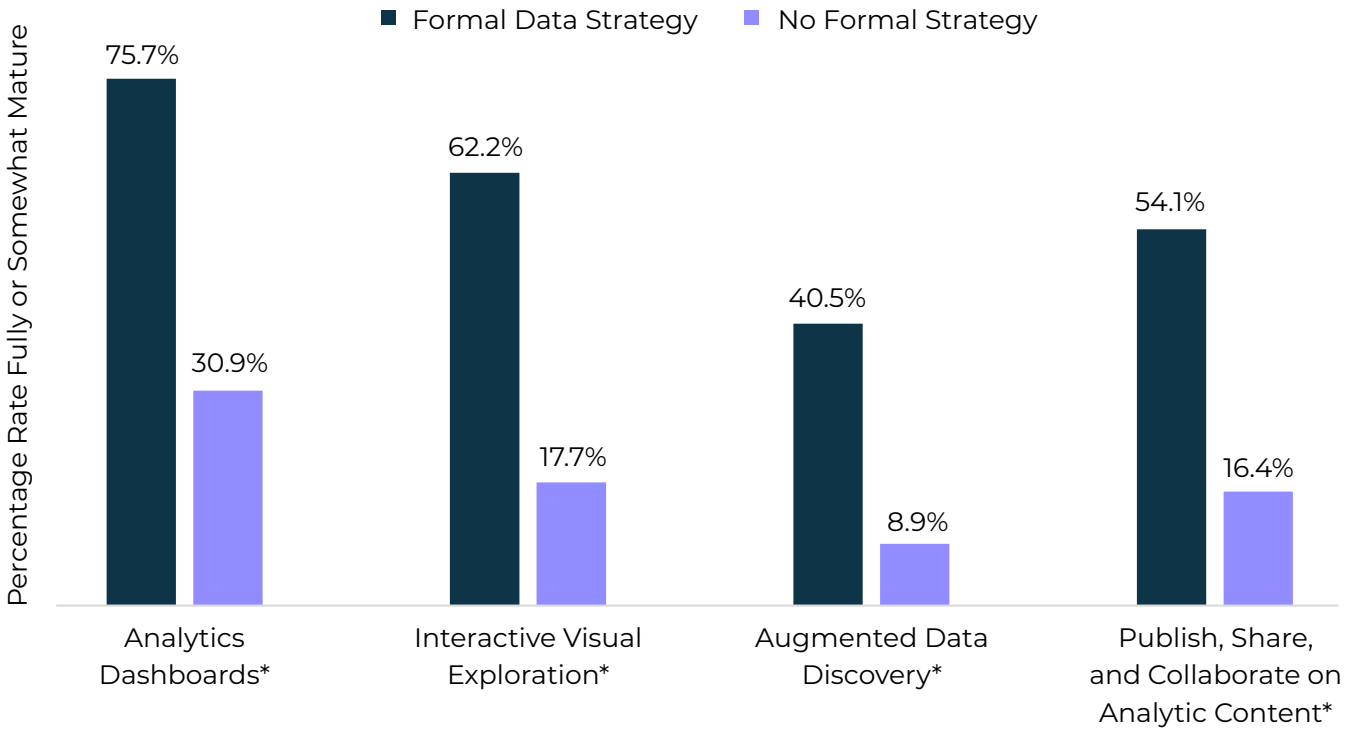
According to a 2021 Gartner Survey of Life Sciences, CIOs funding for digital innovation is growing significantly in 2021 and top investments that Life Sciences CIOs are focusing on include data analytics and process automation.[1] Laying the foundation for expanded artificial intelligence (AI) and analytical capabilities creates a crucial path to reduce the time spent on manual efforts related to clinical data management activities. The groundwork for these advanced capabilities is tied closely with the development of an established data strategy. This is illustrated in the survey results, where 50 percent of respondents with a robust strategy believed their analytical capabilities were more mature. When a data strategy has been executed, organizations are also further along in their plans to research and implement AI, machine learning and deep learning capabilities.

Data sciences competencies are also essential to implement AI models effectively in data related processes. For this reason, life sciences companies with defined data strategies that have enabled them to develop AI and analytical capabilities are also more likely to create dedicated data sciences functions.

The Tufts-eClinical Solutions study demonstrates this, with 47.2 percent of participants that have already implemented a data strategy noting that they also have an established data sciences function in their companies.

[1] Gandhi, A, 2021 Gartner CIO Survey: A Life Science Perspective, February 2021

Data Strategy Advances Analytics Maturity



*Chi-Square Value < 0.05

Advantages in Building AI and Data Sciences Capabilities

An overwhelming majority of survey respondents (85%) see the benefits in developing a strong base for AI and data science capabilities through the implementation of a data strategy. These benefits include improved visibility of data to stakeholders for faster decision making, the ability to leverage clinical data assets, reduced cycle times through more collaboration and shared analytics, cost-savings from resource optimization and reduced rework, and faster acquisition and benefits from new real-world data sources that contribute to development.

> "Data strategy and analytical capabilities go hand-in-hand"
>
> Evolving Clinical Data Strategies and Tactics in Response to Digital Transformation
>
> Therapeutic Innovation & Regulatory Science, 24 August 2020
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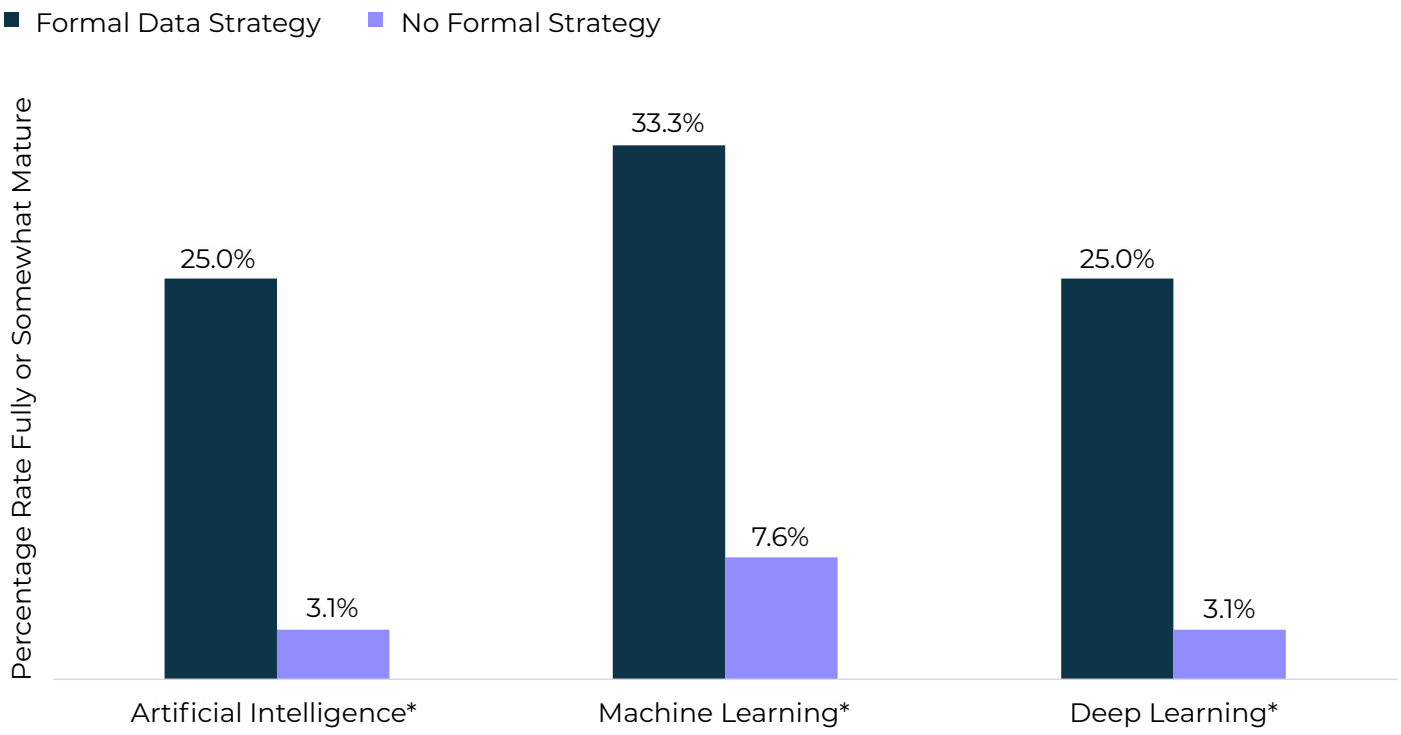
> View paper

Data Strategy Advances Data Science Technology Maturity



*Chi-Square Value < 0.05

Conclusion: A New Era in Clinical Development

> "Data is the currency of Life Sciences"

As the last year has shown, the life sciences industry has reached a new era in drug discovery, where new medicines can rapidly be brought to market safely and effectively under the right conditions. Clinical data has become one of the most powerful assets for life sciences companies representing value today and in the future. As revealed in The Tufts-eClinical Solutions Data Strategies & Transformation Study, the delays that have impeded progress in clinical trials, which have resulted in longer database lock cycle times and the time-consuming, manual efforts related to data review and analysis, will only compound without the adoption of modern digital data management strategies, platforms and processes.

In response to these challenges in the clinical data lifecycle, life sciences leaders are refining their approach and recognizing that changes must be made. Through the implementation of formal data strategies, and the adoption of technologies like the elluminate© clinical data platform, organizations can unlock greater insights from more data streams and improve the speed and efficiency in bringing new treatments to patients.

Related Resources

There are a variety of resources available to use evidence from the Tufts-eClinical Study to support your internal digital transformation initiatives:

- Download the Infographic of Key Study Stats
- Peer-Reviewed Article: Evolving Clinical Data Strategies and Tactics in Response to Digital Transformation, *Therapeutic Innovation & Regulatory Sciences*
- Request a Live Presentation of the Tufts-eClinical Study Data

Accelerate Your Clinical Digital Transformation Today!

Learn more about what it takes to implement a modern clinical data platform to accelerate your data review and analysis processes.

Start your transformation

About eClinical Solutions

eClinical Solutions helps life sciences organizations around the world accelerate their digital clinical initiatives. Our intelligent clinical data platform and data services give our clients real-time, self-service access to all their data from one centralized location; plus advanced analytics that help them make smarter, faster business decisions.

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