RESULTWORKS
Transforming Strategy. Delivering Success.

Transformations

RESULTWORKS NEWSLETTER VOLUME 15 ISSUE 1

OF SPECIAL INTEREST:

- ***Industry trends underlying statistical computing environments***
- ***FDA is driving the industry to deliver increasingly compliant CDISC data and analysis outputs***
- ***A Path to Trusted Data for Better R&D Decision-Making***
- ***A progressive approach to incorporating modeling & simulation into drug development***

INSIDE THIS ISSUE:

ENABLING THE NEXT GENERATION STATISTICAL COMPUTING ENVIRONMENT

Introduction

Statistical analysis has long played a central role in the planning and analysis of clinical trial results. As our scientific information expands and we look for broader relationships across our data, our dependence grows on more advanced information aggregation to enable statistical analysis. Computing environments designed to more broadly handle statistical information and models have become critical for Life Sciences R&D with applicability in:

- Analysis of clinical trial results
- Non-clinical and Clinical Pharmacology analysis
- Translational medicine
- Predictive modeling & simulation
- Analysis of real world evidence (RWE)

By and large, these areas have evolved independently with their own business processes, analyses, and technologies. However, limitations in these environments based on past approaches have become bottlenecks to performing the variety of clinical statistical analyses that would more aggressively advance our modern drug development. Today, we realize that these areas are not so independent after all and there is great benefit to leveraging shared environments designed to support the computing needs required as well as providing opportunities to integrate and analyze data more holistically.

Based on client projects and an industry benchmark conducted, there are numerous trends that are begging some of these challenges while advancing the capabilities and expectations around statistical computing environments.

Current State of the Statistical Environment

As in many parts of R&D, organizations have historically had independence to solve their own challenges and implement their own solutions. Business processes were structured to optimize each group's work flow. Point solutions were developed or purchased to meet the specific needs of each functional area. Much of that technology is now aging and many organizations have reached a point

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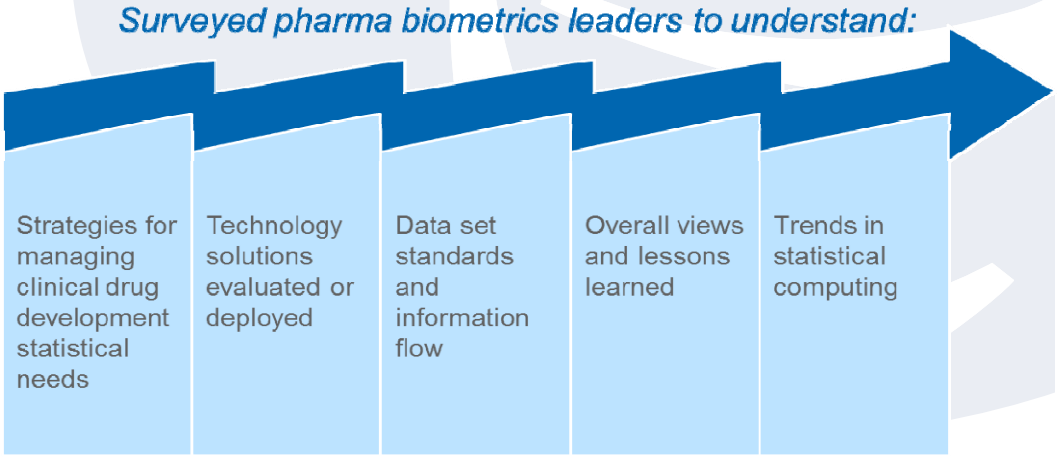
Figure 1: Industry Benchmark Objectives



ENABLING NEXTGEN SCE (CONTINUED FROM PAGE 1)

where decisions need to be made to upgrade what they have or look for new solutions. These same point solutions have also become encumbrances to moving ahead in an integrated way. Today it has become critical to clinical development to assemble and integrate information much broader than many of the traditional functional domains. As a result people are finding themselves spending more time in searching for related data and then working to manually integrate that data into their analyses with tools that are no longer sufficient for today's demands.

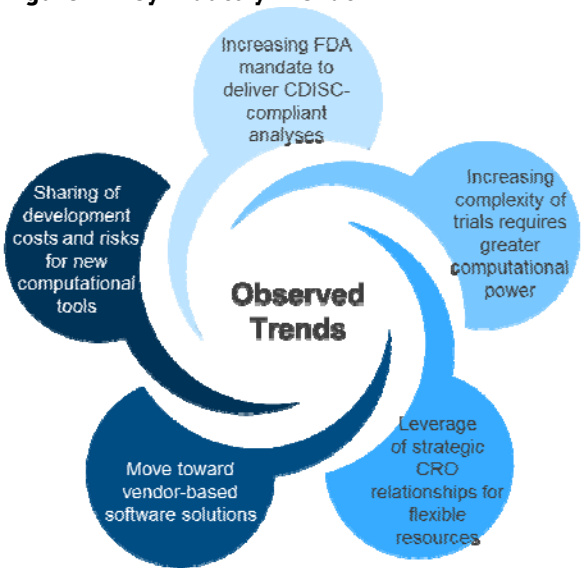
Computing environments designed to handle statistical information and models have become critical for R&D

Industry Perspective

Across the industry, many companies are facing similar challenges. In order to access a broader pool of thinking on statistical computing environments, a benchmark of companies in similar positions was conducted. As depicted in Figure 1, the key objectives of the benchmark were to determine:

- Trends in statistical computing
- Strategies used in managing statistics in clinical development
- Technology solutions evaluated or deployed
- Handling of data set standards and the flow of information

Figure 2: Key Industry Trends



Participants in the benchmark included eight Pharmaceutical companies and one software provider. These companies ranged from some who were just beginning to consider the need to make changes to others who had already invested heavily in changes to their business environment and the supporting technologies employed.

Participants shared views on trends impacting their own future environments which are captured in Figure 2.

First, the FDA is driving the industry to deliver increasingly compliant CDISC data and analysis outputs. It may also soon become necessary to incorporate EHR systems as part of the submission process.

Second, studies are increasing in number and complexity requiring greater computational power than ever before. Adaptive designs are one example of this. Likewise, there is an increased use and support of modeling and simulation (e.g., Model Based Drug Development) tools. With this comes the need for improved metadata management and integration of big data and real world evidence tied to clinical trial data.

As the industry shifts to outsourcing models, there is an increased use of flexible strategic relationships with CRO(s). This drives a need for tighter information exchange with partners as well as data movement approaches that are highly performant.

Interest in development of monolithic custom systems is diminishing. Instead, companies are increasingly reliant on the use of commercial off-the-shelf systems for key components with customization and services to link within the environment.

At the same time, there is a desire to share development costs and risks for new computational tools. The hope is that this will drive costs of tools and platforms down. There is also movement to build industry wide solutions in response to common problems (e.g., TransCelerate).

FDA is driving the industry to deliver increasingly compliant CDISC data and analysis outputs

Specific to their own present course of action, the following themes were prevalent from participating benchmarked companies:

- Moving in directions to lessen dependence on any one vendor and providing the flexibility to model using SAS, R or other emerging capabilities.
- Using a hybrid environment: high performance computing grids coupled with in-house developed services and commercial solutions for their optimum environments.
- Aligning with CDISC standards
- Using of file stores, relational databases and document management systems for source data
- Streamlining work wherever possible through automated workflows, use of standard templates, use of reusable code.

Creating the Vision

With a solid understanding of the statistical environment challenges across the organization coupled with an appreciation of the industry trends, a vision emerged and was adopted by the large, diverse stakeholder community. Characteristics of the vision included:

- Open environments that flexibly integrates preferred tools, applications, analytics
- Agnostic data storage that facilitates access and use
- Fast, scalable, nimble architecture supporting global needs with expected performance

NEXTGEN SCE (CONTINUED FROM PAGE 2)

- Intuitive user interfaces which facilitate efficient use of libraries and automation
- Modern, easy-to-use biometrics work area which improves employee retention and morale
- Effectively handles "big" data
- Balances flexibility with controls, security, and transparency, reducing compliance and IP risk

The vision is summarized in Figure 3. It was supported with an actionable strategy roadmap to realize this vision over a multi-year program.

Conclusions

Like most R&D functional areas, those utilizing statistical computing have been bound by organizational silos. This has led to optimized but narrow business processes, information, and technology use. As our mindsets peak out from those silos and consider broader needs, we are starting to realize that sharing of information, analyses and tools is not only beneficial, but necessary. Trends in the industry spawned by the FDA's drive towards standards, increased strategic relationships, and increased study complexities support this notion.

In order to design better, more integrated statistical computing solutions, consideration of enterprise-wide challenges and broader participation is required. Solutions should be open, facilitate access, be fast, intuitive and yes, modern. Hopefully, industry consortiums will lead to cost effective technology solutions. However, we need to weigh not only the technology but also the breadth of business capabilities, processes, and standards that need to be orchestrated in the new world of statistical computing environments.

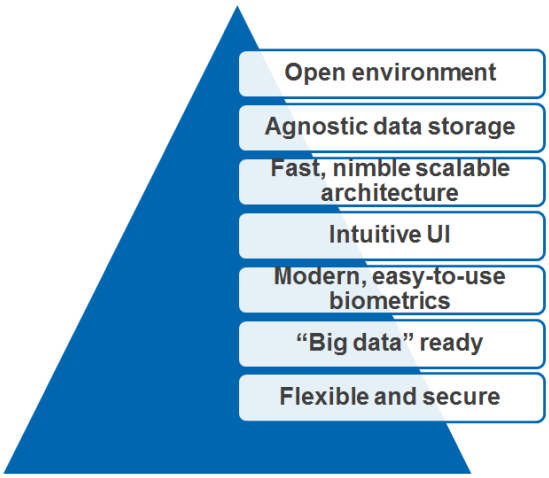


Figure 3: Vision for SCE

DATA QUALITY FRAMEWORK POSTER

ResultWorks' poster on Data Quality Framework continues to be very topical with the emphasis in the industry on data governance, data sciences, and in general, better R&D information management.

Pictured in Figure 4 is the poster entitled " Data Quality Framework: A Path to Trusted Data for Better R&D Decision-Making." The framework was developed for a client program to provide a foundation for data quality excellence by designing a methodology for data quality management and governance. The framework became the basis for conducting ongoing data quality projects.

Some of the benefits include:

- Improves data quality such that the organization can implicitly trust its information
- Reduces the resources and effort needed in association with making data-based decisions by making it easier to aggregate and reuse data for different purposes
- Increases the accuracy of data-driven decisions

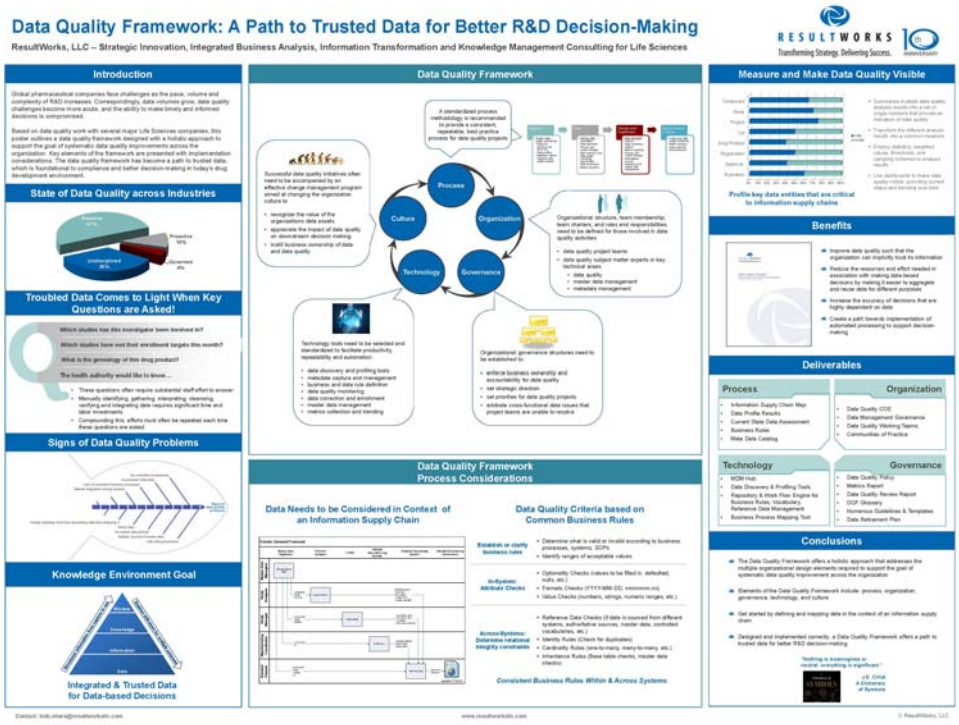


Figure 4: Data Quality Framework Post-

The Data Quality Framework offers an approach that addresses multiple organizational design elements required to support a goal of systematic data quality improvement across the organization.

For an electronic copy of the poster please contact Bob O'Hara via our marketing email link.

RESULTWORKS
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DELIVERING SUCCESS

Several new ResultStories, ResultWorks' project briefs based on real world successes, have been added recently to our website.

Highlighted here is a ResultStory describing a "Cross-Functional Information Transaction Mapping" project. ResultWorks mapped the primary and secondary business transactions and information flows for the biologics unit of a major Pharma company. Based on this mapping, numerous information logjams were identified and prioritized.

The ResultSession provided substantial validation of our thinking while at the same time provided some intriguing implementation concepts we had not considered .

A strategy framework was then developed to balance technology investments in solving immediate functional needs while at the same time improving broader long-term information management objectives.

MODELING & SIMULATION WHITEPAPER

The challenges faced by the life sciences industry are well documented – declining NDA's, more complex clinical trial programs, and overall increasing costs with diminishing successes. Over the last five to ten years, pockets of change have emerged in simulating clinical trials and clinical trial programs, and organizations willing to utilize them. For those who have persevered and evolved with the technologies, the returns have been significant, including reductions in time and cost, and improved decision-making based on scientific data.

This paper proposes a progressive approach to addressing drug development challenges. It is couched in a proposed clinical trial design maturity model which allows for incremental use of effective simulation technologies. Key to the success of the technologies is the organizational commitment to shifting from the current state to increasingly mature methods. This affects culture, organization, people, and process. Over time these technologies are incorporated into individual trials and ultimately into entire clinical trial programs where the returns can be impressive.

ResultWorks' whitepaper entitled "Maturing the Clinical Trial Design Process—Harnessing the Power of Modeling and Simulation" is now available on our website.

MYTHS OF STRATEGY EXECUTION

Involved as ResultWorks is in R&D strategy projects, strategy is just the beginning; not the endpoint. Execution is the greater challenge which does not happen by itself. In a Harvard Business Review article this March "Why Strategy Execution Unravels—and What to Do About It", the authors present four myths about strategy execution:

Myth 1: Execution Equals Alignment
Myth 2: Execution Mean Sticking to the Plan
Myth 3: Communication Equals Understanding
Myth 4: Performance Culture Drives Execution

Interestingly, they cite several statistics based on survey work that 84% of managers say they can count on their bosses and direct reports to execute against a strategy. However, only 9% believe they can rely on colleagues in other functions. Given the current era in Pharma where strategies are tackling broader cross-functional changes, we are likely to be facing uphill struggles unless we can improve in this area.

(To read the full article, click on the link in the title above.)

RESULTWORKS NEWS

Recent and Upcoming Events & Activities:

- Greater Philadelphia Senior Executive Group (GPSEG): Panel on "Tuning your Consulting Relationship" - ResultWorks on the panel with diverse Life Sciences Executives
- Hosting GPSEG presentation: Personalizing Personalized Medicine presented by Dr. Fredric Abramson
- Presenting two posters at Bio-IT in April on statistical computing environments and sample management

Current / Recent Client Initiatives:

- Clinical Sample and Assay Data Management Strategy
- Statistical Computing Environment Strategy and Roadmap
- Compound Management Definition and Solution Selection
- Electronic Documents Strategy & Requirements Definition
- Process, information, and enterprise architecture strategy for seamless R&D and Manufacturing

ABOUT RESULTWORKS

ResultWorks is a professional services company offering strategy innovation, integrated business analysis, information transformation, and knowledge management consulting services for the life sciences industry. Results are achieved through skilled facilitation and exceptional management leadership. The focus of our client engagements is optimizing life sciences effectiveness across research, development, clinical, regulatory, and manufacturing.

Contact Us:
1060 First Avenue, Suite 400, King of Prussia, PA, USA 19406
Phone: 610-688-5870
Email: marketing@resultworksllc.com
Website: www.resultworksllc.com