Thinking Big in Biotech

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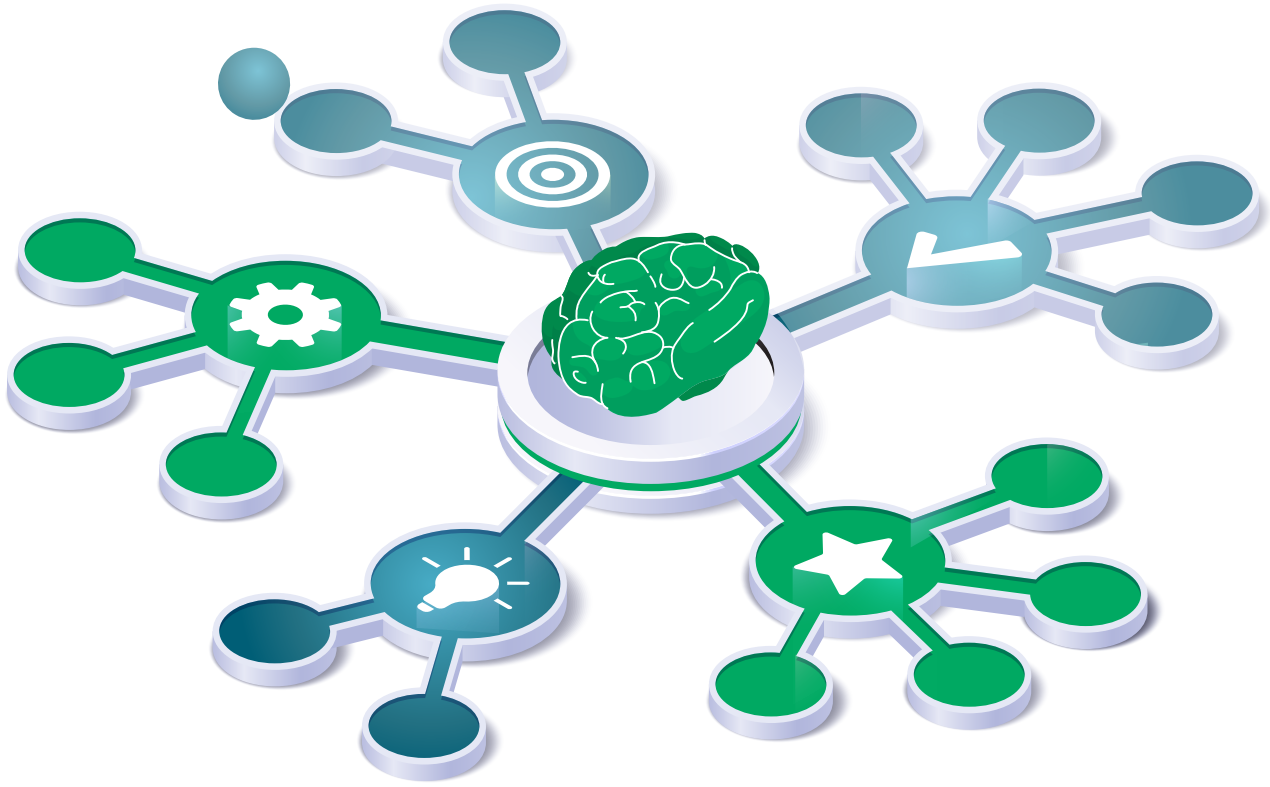
The Power of Predictive Analytics for More Effective Drug Development

With limited resources and stiff competition, small- to mid-sized biotech companies have to make every data point count.

Clinical technology powered by artificial intelligence (AI) enables lean biotech teams to do just that. With the right data analytics platform, biotech sponsors and their CROs can improve trial performance, ultimately moving to database lock faster. They can also identify and mitigate potential risks early in the trial process, lowering the odds of delay or failure. When equipped with advanced AI techniques, a data platform can generate insights that inform future trials.

While many clinical technology platforms offer real-time data monitoring and analytics, predictive capabilities are an emerging technology in the clinical space. According to a survey conducted by WCG Center Watch, 83% of sites, sponsors, and CROs surveyed said they use AI and machine learning (ML) in some way. Less than 7% leverage predictive analytics for research[1].

A transformative approach is required to effectively implement real-time and/or predictive analytics into clinical development. The benefits of this approach can pay off in dividends for years to come.



1. https://www.centerwatch.com/articles/25428-industry-using-aiml-to-improve-data-quality-and-trial-management-survey-says

Real-Time Analytics

Real-time analytics applies logic and mathematics to data, delivering insights to help you make better decisions quicker than with manual methods[2]. Many clinical technology platforms offer some type of real-time analytics, whether for monitoring, reporting, or both.

Applications in clinical research include:

- Identifying issues with protocol compliance
- Identifying data anomalies, such as abnormally high or low lab values
- Automated on-time site payments
- Budget tracking
- Up-to-date reporting
- Remote patient monitoring
- Automating data cleaning for higher data quality

2. https://www.gartner.com/en/information-technology/glossary/real-time-analytics

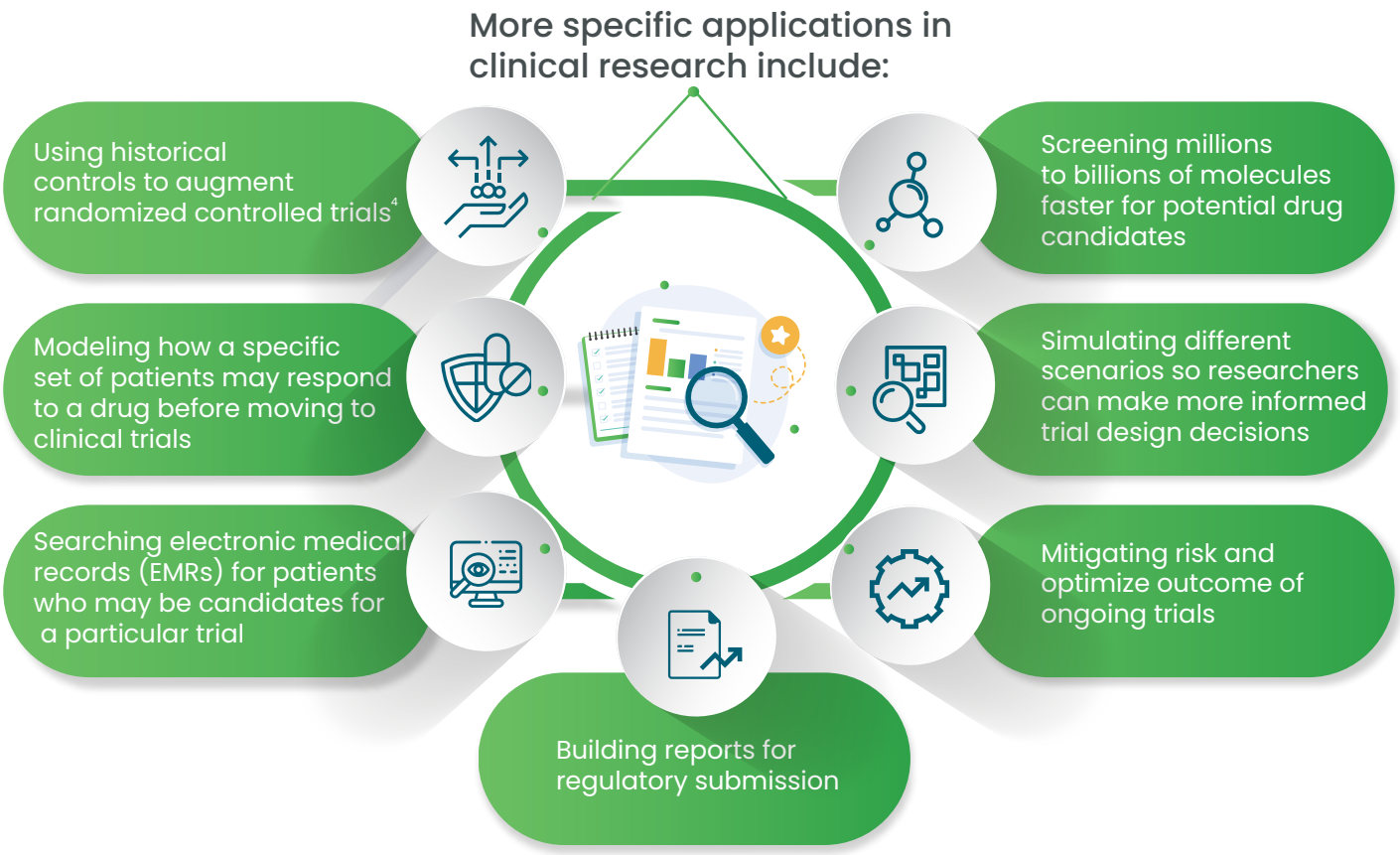
Predictive Analytics

is your crystal ball. Predictive analytics is an advanced computing technique that makes predictions about future outcomes. This is achieved by using large amounts of historical data to train algorithms to recognize patterns. By looking at patterns, the tool predicts the likelihood of whether something may or may not happen in the future[3].

Biotech sponsors can use AI and predictive analytics at the following points in the drug development lifecycle:

- For trial design and planning before launch
- For risk detection, mitigation, and outcome optimization during a clinical trial
- For gaining insights on study endpoints, as well as safety and efficacy, for timely submission after trial completion

3. https://www.ibm.com/topics/predictive-analytics



Few clinical technology platforms offer advanced predictive analytics that accommodate the applications above. To access these fortune-telling capabilities, biotech companies would ideally partner with a vendor that offers predictive analytics capabilities as part of a unified data capture and management platform.

Biotech sponsors can also license data analytics software from a different vendor; however, this option may introduce data compatibility issues. Considering the complexity already inherent in setting up AI-enabled systems and processes, an "a la carte" approach may put unnecessary strain on IT staff and partners.

Advantages of Predictive Analytics in Clinical Research

Predictive analytics tools sift through vast amounts of data to identify patterns within. These tools then assess those patterns and offer assessments or suggestions, helping biotech sponsors identify potential risks, such as patient safety issues, protocol compliance risks, and data quality risks, among others.

Predictive Analytics for Data Quality

How much time does your study team spend on data cleaning? Modeling technologies such as machine learning allow sponsors to automate that process, reducing cycle times by weeks and freeing up staff for higher-value activities. Automating data cleaning also helps reduce risk of manual error, leading to improved data quality.

4. https://ojrd.biomedcentral.com/articles/10.1186/s13023-020-1332-x

Predictive Analytics for Cycle Time Improvement

Among other benefits, digital technology has the potential to help drug, device, and biologics developers get their products to market faster[5]. Sponsors can use predictive analytic techniques in several ways to reduce clinical cycle times.

A few common scenarios include:

Identifying targeted patient populations

Studies have shown that for every patient who responds favorably to a study drug, there are 3 to 24 who do not. Machine learning helps improve those odds. These tools can analyze genetic data, EMR data, and prior study data to identify patient populations more likely to respond favorably to a drug. With a higher ratio of responders, sponsors can run smaller and more targeted trials[6].

Simulating trial scenarios

Predictive analytics enable researchers to test certain scenarios to determine the most effective approach. For example, these tools can analyze real-world data to identify specific groups of patients with unmet needs—potentially good targets for future clinical trials. Machine learning-based tools can also help researchers with secondary trial analysis. Sifting through data faster than humans, the technology can identify treatment heterogeneity while providing some protection against false-positive discoveries.

5. https://www.nature.com/articles/s41746-020-0302-y
6. https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-021-05489-x

Predictive Analytics for Risk-Based Management

Predictive analytics provides early warnings to help mitigate risk related to patient safety issues as well as trial delays.

AI algorithms can predict the possibility of adverse events before proceeding to clinical trials. By addressing potential safety issues before they occur, sponsors have the ability to execute trials with fewer adverse events and/or reactions. This leads not only to better trial results but lower remediation costs.

On the operational side, AI/ML-based tools can serve as a component of risk-based management strategies. The models have the capability to identify risk early in the research cycle. This approach allows for proactive course corrections in trial protocol and strategy, saving time and resources while complying with FDA guidance.

How to Implement Predictive Analytics into Your Clinical Research

Small- to mid-sized biotech companies can harness the predictive power of data analytics even if they have limited resources to run clinical trials. A few options include:

Build software in house
This option works if you have an experienced team of data scientists and engineers. Otherwise, the expense of designing, training, and validating the algorithms, followed by testing and implementing the system, makes this approach less feasible.

Use your CRO's system
This option works if your CRO has sophisticated data capture and management technology with both real-time and predictive analytics capabilities. The CRO must also have the technical know-how to deliver quality data and relevant clinical insights. However, depending on the CRO, you may have less control over your data if you take this path.

Take a "best of breed" approach
Large pharma/biopharma companies often combine new technology with the systems they've always used. This "best of breed" approach involves less change management, but it creates data silos that limit the potential of analytics. It also increases the workload for clinical operations teams and site staff who must learn, log into, and manage multiple platforms for one study.

Use an end-to-end platform
To eliminate data silos, lessen site staff and ClinOps workload, retain control of your data, partner with a clinical technology company that offers the tools you need to execute and analyze your clinical trials from start to finish. With unified data capture, data management, and predictive analytics capabilities, you can implement proactive strategies to run more cost-effective and efficient clinical trials.

MaxisIT's Clinical Trials Oversight System (CTOS)

MaxisIT's SMART Optimizer is a game-changing tool with real-time machine learning and simulation capabilities that lie within our Clinical Data and Analytics Platform. This powerful solution enables clinical trial sponsors to review and compare ongoing trials against their plans, forecast key study events based on current performance, detect risks, and optimize strategies to mitigate those risks.

MaxisIT's CTOS helps the industry transition from an oversight to optimization mindset. With CTOS, sponsors can better navigate the unpredictable challenges in the clinical trials, including patient enrollment variations across regions, countries, sites, and therapeutic areas.

To stay ahead in this ever-changing landscape, it's time to leave reactive approaches behind and embrace a transformational strategy—a strategy that allows sponsors to predict challenges and optimize trial outcomes.

Conclusion

To develop the most effective products faster, it's time for the biotech industry to shift from a "sense and respond" approach to a "seek and act" philosophy. Machine learning and other AI-based techniques enable that proactive approach, resulting in higher-quality data, quicker cycle times, and more streamlined risk assessment and mitigation. In the crowded race to market, consider analytics a powerful engine to accelerate the journey from preclinical research to New Drug Application (NDA) or Biologics License Application (BLA).

About MaxisIT

MaxisIT's purpose-fit and intelligent clinical data analytics platform helps improve clinical trial performance, mitigate risk, and optimize clinical outcomes. We provide a centralized and reliable source of truth for diverse data types from various sources, giving life sciences companies real-time insight to shorten cycle time and increase return on investment.

Incorporating an end-to-end clinical data pipeline from intake to visualization, MaxisIT's solutions are powered by AI/ML and metadata-centric approaches. Our impressive portfolio of over 3,300 clinical trials and an unparalleled 100% customer retention rate affirm the quality and reliability of our services.

Moulik Shah
Founder & CEO, MaxisIT

Moulik Shah is a passionate healthcare technology entrepreneur and the visionary CEO of MaxisIT, where he has been at the forefront of leveraging technology to transform pharmaceutical and life sciences clinical trials.

His dedication to improving patient outcomes and his leadership in directing patient-centricity, patient diversity, interoperability, and real-world-data-led collaborations have been at the core of his vision of an integrated healthcare ecosystem based on effective use of data and analytics platforms.

He has been instrumental in driving innovation and progress in the industry. Under Moulik's leadership, MaxisIT has become a leading provider of clinical data and analytics which is driving real-world impact in the pharmaceutical and life sciences clinical trials.

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