MEDIDATA | acornai

GAINING THE INSIGHT TO OUTPERFORM

Medidata's guide to unlock every trial's full potential

TABLE OF CONTENTS

INTRODUCTION

Biopharma organizations are under increasing pressure to effectively leverage an expanding set of research, clinical, operational, and real world data (RWD) to accelerate their trials and improve their chances of successfully launching new drugs. While data and advanced analytics hold great potential, accessing fit-for-purpose data sources, standardizing and integrating datasets, deriving actionable insights, scalability, and change management are major challenges along the way.

MEDIDATA'S OUTLOOK

We see a 60% increase in procedures over the last 10 years, and a 25% increase in planned visits on an average protocol. That's more time. That's more cost. That's more burden on investigators and patients. We've developed a way to objectively look at a protocol and understand how those procedures are aligned to core and secondary objectives, which ones don't align to core objectives, what the relative complexity of those procedures are, and what the impact is on cost, on investigator burden, and on patient burden.

Poor operational outcomes have been a persistent and growing issue in the industry; 57% of trial protocols have at least one significant amendment that causes delays of more than three months, at a median direct cost of $500K each for a Phase III protocol. 90% of all trials are not able to enroll patients within target timeframes; each day a trial delays a drug's time to market costs sponsors between $600K and $8M. These issues are further compounded by the impact of the COVID-19 pandemic on study starts, enrollment, and visits.

AI-enabled technologies and advanced analytics unlock insights that drive far-reaching efficiencies. If drug development is going to catch up to the digital age, cross-industry data, advanced analytics, and AI become a true necessity. With fit-for-purpose data sources at hand, life science companies can better analyze clinical trial data and real world data to build predictive models in ways that traditionally have not been possible. While many life science companies are making great strides in applying analytics to the data from their own trials, larger, high-quality datasets are needed.

Medidata Acorn AI Intelligent Trials, our offering for operational analytics, delivers insights to improve the speed and success of trials through better study design, enhanced country and site selection, enrollment predictions, and real-time study tracking against other similar industry trials. Acorn AI Intelligent Trials is built on Medidata's platform and one of the industry's largest clinical trial operational performance data assets–covering 23,000+ trials and 22,000 healthcare facilities with associated investigators across 94 countries. Intelligent Trials empowers sponsors to expand their access to real-time performance data and leverage high quality insights to improve their operational decision-making.

In this eBook, discover how to improve study success rates, optimize study design, accelerate enrollment, monitor performance against similar trials, and uncover issues for early remediation with Intelligent Trials.

GAIN THE INSIGHT TO OUTPERFORM

Gaining insights to win more bids and stand out from the competition is imperative for CROs. Securing and expanding their sponsors and studies ecosystem determines how they will outperform the competition.

Acorn AI Intelligent Trials powers CROs with the insight to outperform by leveraging unique performance data and advanced analytics across three critical areas – Study Design, Operational Feasibility and Trial Performance. CROs can not only improve sponsors' performance, they also differentiate themselves in an ever-competitive industry environment.

Intelligent Trials' out-of-the-box solutions improve operational outcomes by providing cross-industry performance metrics, predictive models, and forecasting capabilities. The full suite of offerings for Intelligent Trials includes Study Design, Study Feasibility, and Performance Analytics.

Future-proof studies by optimizing protocol to balance scientific needs and operational efficiency with Study Design

Design more operationally efficient and patient-centric trials by understanding the impact of design decisions. Quantify and benchmark study complexity, site effort, patient burden, and costs. Reduce risk of poor patient recruitment and retention. Assess impact of inclusion and exclusion criteria on available patient population.

Accelerate enrollment through more precise study, country and site insights driven by cross-industry performance data and predictive models available in Study Feasibility

With Study Feasibility, leverage historical performance metrics from over 20,000 clinical trials, predictive models demonstrated to enhance decisions, and competitive congestion metrics. Metrics include study, country, and site-level performance (milestones, screen failure, enrollment, quality, etc.), including inbuilt comparisons against the industry. These insights result in greatly improved precision in the planning process, a broader perspective across country and site performance, and faster enrollment with reduced timelines.

Track trials against other live trials and changing industry conditions to identify issues early and remediate with Performance Analytics

Rapidly assess past site performance to predict future performance, identify issues early, and recommend actions to keep trials on track. Performance Analytics provides dashboards to monitor and manage performance for single trials and across portfolios with tracking against industry benchmarks. Intelligent Trials is the only AI solution that provides the real-time visibility into trial and site performance.

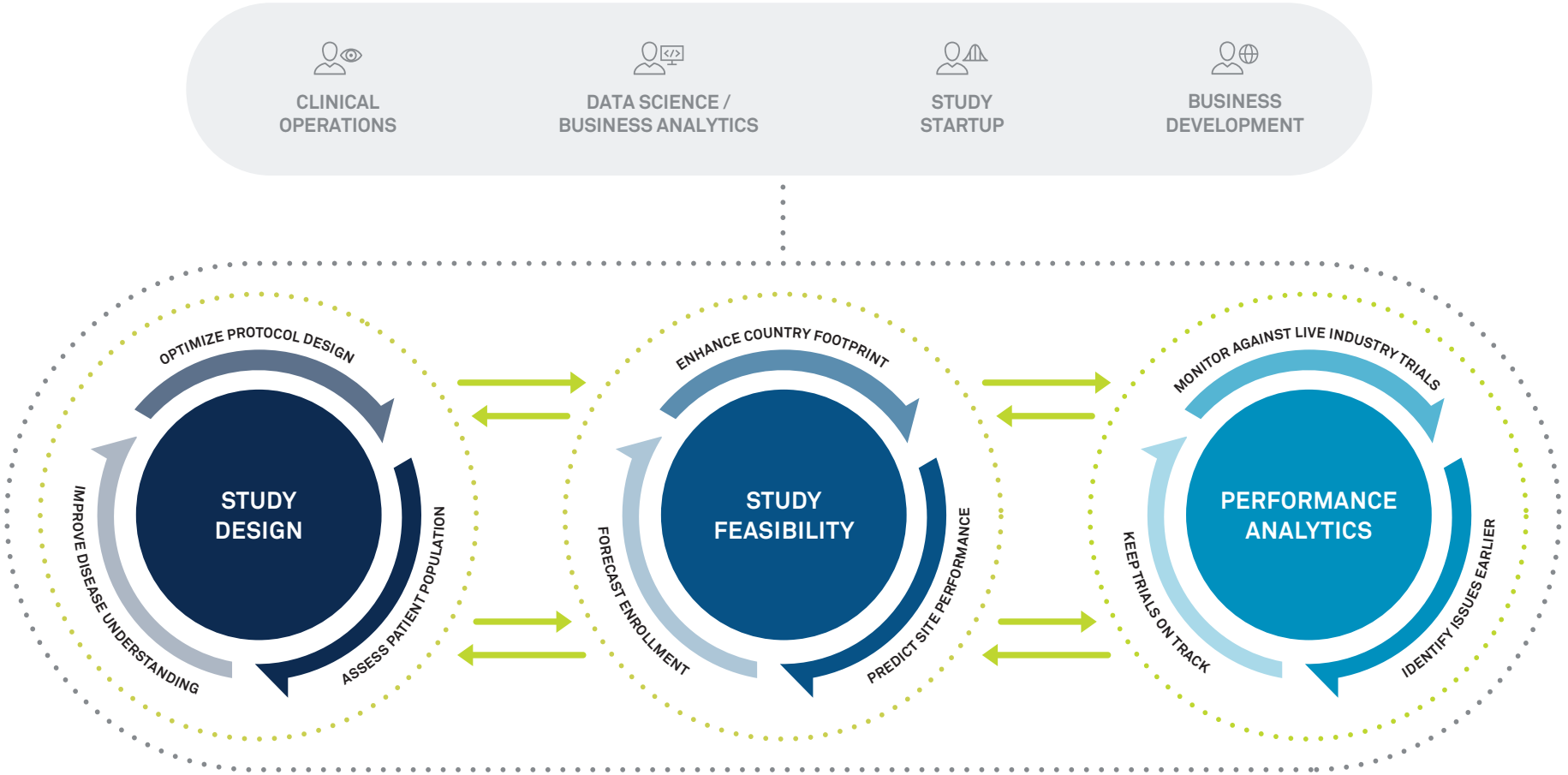
MEDIDATA'S OUTLOOK

We complement customers' data with fit-for-purpose data from other trials being conducted on our platform. We then build new predictive models together to answer critical questions about study or site feasibility, enrollment, or trial performance. We don't want to overwhelm customers with too much data or with information that they can't process, so we bring it all together to simplify decision making.

MORE PRECISE, DATA-DRIVEN DECISIONS ARE NEEDED TO HELP:

Reduce protocol amendments	Accelerate enrollment	Reduce cost
Ensure data quality	Reduce patient burden	Bring drugs to market faster

Let's take a look at how Acorn AI Intelligent Trials is the insight engine that improves study success rates, optimizes study design, accelerates enrollment, monitors performance against other similar trials, and uncovers issues for early remediation. Intelligent Trials creates more patient-centric trials and leverages advances in technology, data engineering, and data science to drive operational improvements.



MEDIDATA'S OUTLOOK

We're able to look at protocol against competitive trials. This allows us to think about the investigator and the patient journey in a more quantitative way. We map the trial journey and gain insights visit by visit. What are the costs associated with that visit? Was the investigator burden associated with that visit? And what is the patient burden associated with that visit?

CUSTOMER SUCCESS STORY

A sponsor was looking to optimize their study design and streamline their clinical procedures. When we provided them with benchmarks of other ongoing trials in the space, they decided to change protocol at their Day 120 visit. As we dug deeper, we realized many of these procedures weren't related to the primary or secondary objective. The sponsor made a strategic decision to pull back and eliminate some procedures to drive a more patient-centric trial.

Outpace Your Competition

Drive competitive advantage

Attract more bids and stand out from the competition with access to the industry's best data repository and pre-built analytics. Lead the way in trial performance with a data-driven planning approach to reduce trial complexity and improve disease understanding, resulting in faster trial timelines, increased win rates, and lower costs.

Preserve margins

Site selection without integration of real world and site performance data limits patient availability and enrollment, jeopardizing trial success. Instead, leverage our platform to gain a holistic perspective on site selection and patient populations. Our industry wide aggregated data and out-of-the-box analytics will help secure higher patient enrollment and retention, giving you a competitive edge.

Rapidly identify target patients

Restrictive inclusion and exclusion criteria limit patient availability and enrollment, jeopardizing trial success. Instead, leverage RWD to model how layering different inclusion and exclusion criteria affects patient availability. Intelligent Trials' industry-wide aggregated data and out-of-the-box analytics ensures that complex protocols do not hinder patient enrollment and retention.

Be Precise With Your Study Feasibility

Identify optimal countries to enhance footprint

Our experts assess your country footprint to identify optimal countries and sites while balancing speed, cost, and quality. With Intelligent Trials, pinpoint additional countries to consider for your trials with a focused effort on accelerating enrollment.

Act on predictive data patterns

Access predictive models built on hundreds of features including performance, congestion, quality, and capacity to better segment and select sites. Our team of industry experts, data scientists, technologists, and ex-regulatory officials identify sites and investigators with higher expected enrollment performance given your trial's characteristics and the competitive landscape.

Accelerate enrollment with forecasting capabilities

Rather than waiting for problems to arise, generate forward-looking insights that accelerate patient enrollment based on historic performance, predictive models, and industry trends. With data-driven country and site selection, identify high-enrolling sites to increase patient availability and trial enrollment at site, country, and trial level.

MEDIDATA'S OUTLOOK

Our predictive models allow you to identify sites that are likely to enroll well and those that are non-enrolling. When you rely on historical site level data to predict your next site, it only gets you part of the way. Historical site performance alone has less than 30% predictive power in some indications. Instead, we need to layer on other features that are specific to the trial itself: what are the details of the protocol? What is the congestion of that site? How many trials does it run? How many trials are being run in the area around it? When we think about patient availability, we also look at the sponsor and the CROs involved. Sites have different relationships with different sponsors, and they enroll them differently. Use that data to tease those relationships apart and understand the best sites for your trial.

MEDIDATA'S OUTLOOK

Making data-driven decisions across the value chain of a trial creates real impact. Using our robust datasets, design better trials that reduce protocol amendments, choose better investigators and sites to accelerate enrollment, and drive efficiency in your processes to reduce cost. Better data analysis ensures data quality and readily identifies outliers, ultimately creating trials that are better for investigators and patients.

Remediate Studies in Real Time

Monitor performance and competition in real time

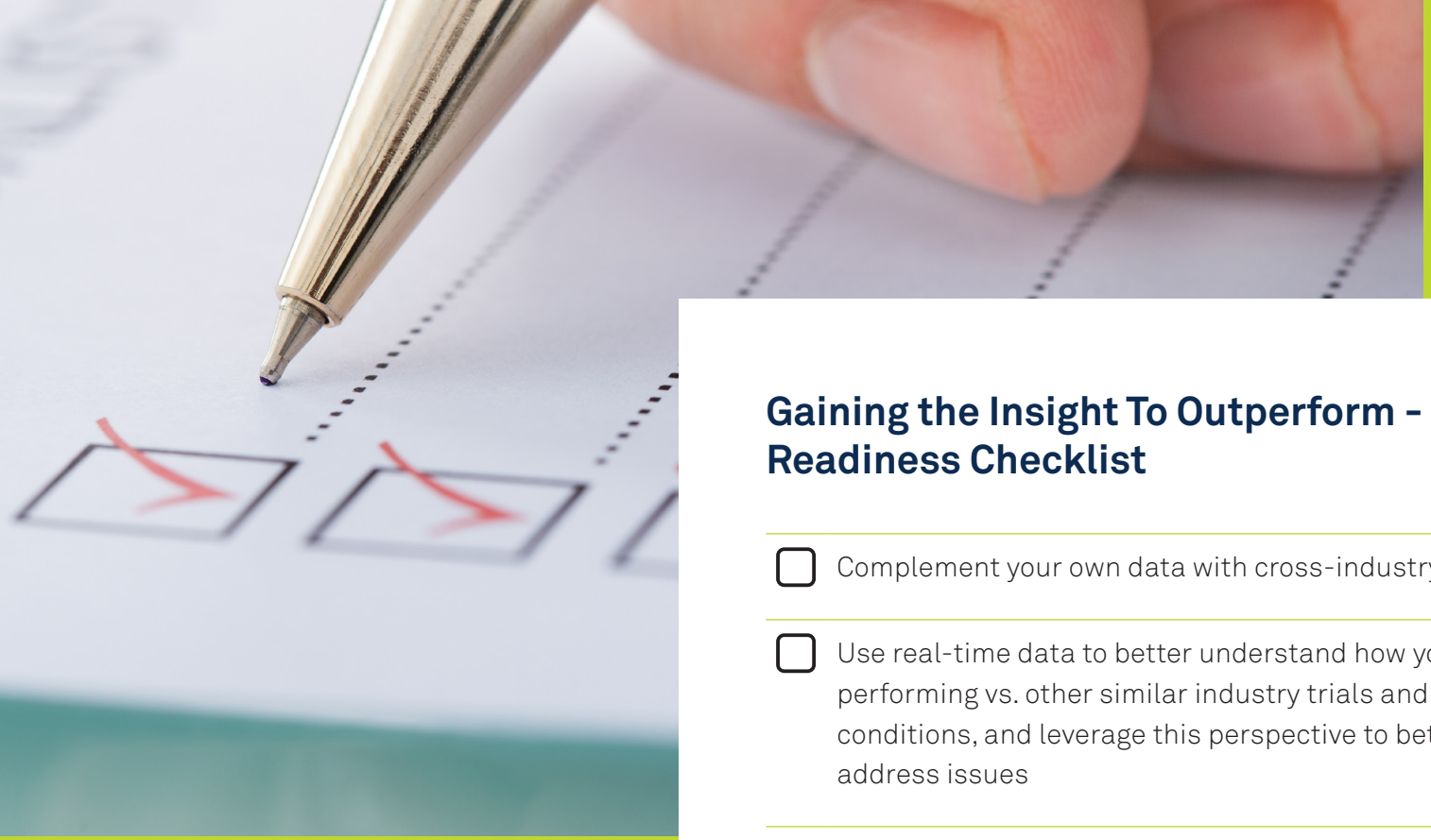
Leverage the only player with real-time study and site-level performance insights, providing comprehensive trial analysis against benchmarks and competing sites. With enrollment and congestion tracking, gain a better understanding of competition at your sites and receive alerts based on changing industry conditions.

Identify issues early and diagnose

Gain early insights into changing industry conditions with Intelligent Trials, run with real-time trial monitoring, diagnostics, and benchmarks. A centralized view across all trial portfolios gives you the increased agility and understanding to improve operations and intervention strategies.

Course-correct to keep trials on track

Use advances in technology, data management, and analytics to uncover issues early and course-correct in real time. Resolve deviations upon identification with Intelligent Trials' early-detection capabilities, and take immediate action to design better patient-centric experiences.



Gaining the Insight To Outperform – Readiness Checklist

- [ ] Complement your own data with cross-industry datasets[1]
- [ ] Use real-time data to better understand how your trials are performing vs. other similar industry trials and changing industry conditions, and leverage this perspective to better diagnose and address issues
- [ ] Construct a lean study design that achieves the essential clinical and statistical outcomes without exacerbating patient and site burden
- [ ] Increase patient recruitment, retention, and adherence by systematically evaluating patient burden[2]
- [ ] Access historical and predictive performance data on sites to optimize country and site selection
- [ ] Predict and forecast enrollment at site, country, and trial level[3]

1. Medidata has the largest, standardized, clinical trial performance data repository captured across 23,000+ clinical trials and touching 7+ million patients across 22,000 sites and 94 countries

2. Medidata's Patient Burden Index, or PBI, is an effective tool to quantitatively access patient burden to improve trial design, downstream operations, and patient centricity

3. Medidata can help you identify optimal countries and sites while balancing speed, cost, and quality

GAINING THE INSIGHT TO OUTPERFORM

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,700 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at **www.medidata.com** and follow us **@medidata**, The Operating System for Life Sciences™.

info@medidata.com | +1 866 515 6044

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