Data is the Future of Clinical Trials

CRO Edition

Deliver on sponsors' timelines while shortening study start time, optimizing study design, and improving trial performance

The reality of COVID-19 is that it has permanently changed the management of clinical trials. There will not be a return to pre-pandemic methods for study design and execution. CROs are being pressured to modernize their use of technology and data in order to adapt to this new paradigm. Study success is now grounded in the ability to gather and analyze data to identify trends, locate actionable insights, and make real-time decisions.

Leveraging clinical trial operational performance data assets to better design a study, improve its feasibility, and monitor performance is essential.

> **AI-enabled technologies and advanced analytics empower CROs with real-time performance data and high quality insights to improve their operational decision-making.**

Gaining the ability to detect errors, trends, and anomalies to proactively perform root cause investigations and take corrective actions throughout the study is as critical.

> **Using machine learning, CROs have the ability to continuously scan and detect errors, trends, and anomalies in study data to improve data quality and ensure patient safety.**

This eBook is an overview on how CROs can lead with data to improve their study integrity, reduce risks, optimize patient safety, and increase their trial success rates.

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STUDY DESIGN

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Every delay in trial completion due to issues with protocol development, lack of patient diversity, amendments mid-trial, and / or lack of patient enrollment not only slows therapeutics from being delivered into market, but has a significant economic impact.

Acorn AI's Intelligent Trials solution provides an analytics platform to improve the speed, success, and quality of trials, built on a foundation of industry-leading data from across 20,000 clinical trials.

Intelligent Trials solutions allow you to optimize trial design, select top performing countries and sites, and ensure performance of your trials once they launch.

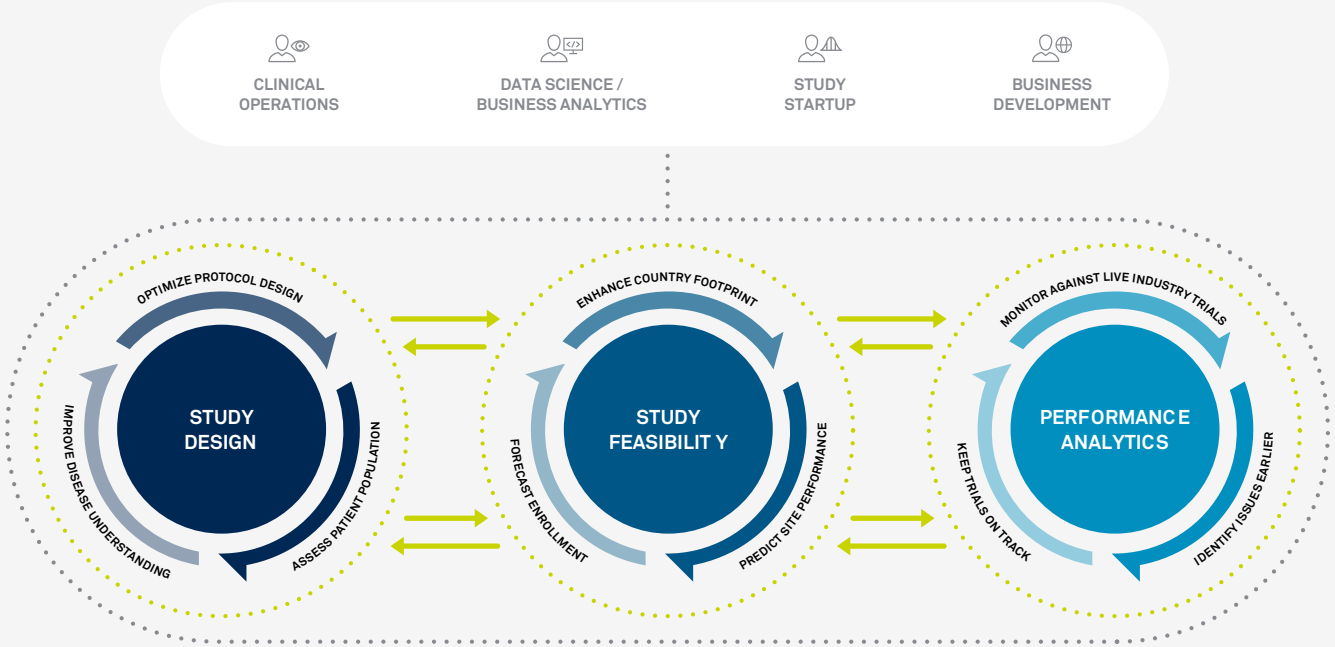
Improve your trial success rates by optimizing study design, accelerating enrollment, monitoring performance against similar trials, and uncovering issues for early remediation.

57%
of trial protocols have at least one significant amendment that causes delays of more than three months

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 your clients between $600K and $8M

ACORN AI POWERS THE INSIGHT ENGINE FOR INTELLIGENT TRIALS

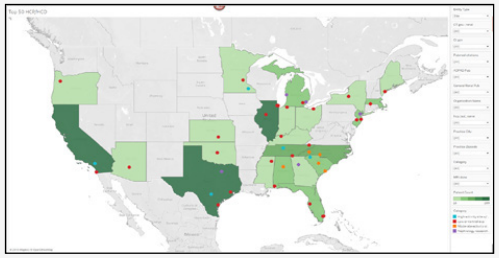


Are you able to look at protocol against competitive trials?

Can you map the trial journey and gain insights visit by visit?

What are both patient burden and investigator burden associated with each visit?

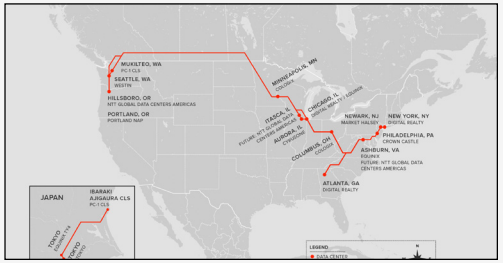
What are the costs associated with each visit?



IDENTIFY TARGET PATIENT POPULATIONS

Use RWD to understand patient populations and impact of inclusion/exclusion criteria

Link to operational design and required site characteristics support site selection



OPTIMIZE DESIGN

Measure and benchmark site burden and patient burden

Optimize protocol to balance scientific needs and operational efficiency

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

Plan for greater trial performance

Improve patient centricity

Rapidly identify target patients

- Plan for greater trial performance and patient-centricity 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

2 OPERATIONAL FEASIBILITY

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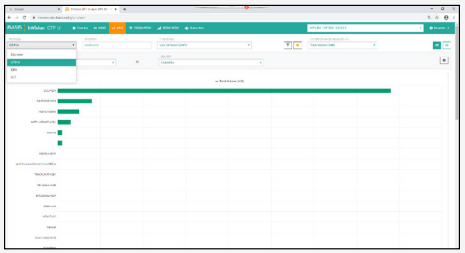
What are the details of the protocol?

What is the congestion of each site?

How many trials do your sites run?

How many trials are being run in the area?



ACCELERATE ENROLLMENT

Identify optimal countries and sites balancing speed, cost, and quality

Predict enrollment at site, country, and trial level

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

Identify optimal countries to enhance footprint

Act on predictive data patterns

Accelerate enrollment with forecasting capabilities

Study Feasibility helps organizations leverage historical performance metrics from 20,000+ trials and 22,000 healthcare facilities with associated investigators across 94 countries.

Metrics include study, country, and site-level performance (milestones, screen failure, enrollment, quality, etc.), including inbuilt comparisons against the industry.

Predictive models enable CROs to identify sites that are likely to enroll well and those that are non-enrolling.

These insights result in improved precision, broader perspective across country and site performance, and faster enrollment with reduced timelines.

TRIAL PERFORMANCE

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Do you have a clear understanding of your competition at each site?

Do you get real-time alerts about evolving industry conditions, e.g., COVID-19 and competitive trial updates?

Can you make data-driven decisions across the value chain?

MONITOR PERFORMANCE

Focus effort to improve operations with a centralized view across trials

Real time tracking of performance against industry benchmarks and other active studies

Remediate Your Study in Real Time with Performance Analytics

Monitor performance and competition in real time

Identify issues early and diagnose

Course-correct to keep trials on track

Better data analysis ensures data quality and readily identifies outliers, ultimately creating a better trial for investigators and patients.

With enrollment and congestion tracking, you gain a better understanding of competition at your sites and receive alerts based on changing industry conditions.

Leverage real-time trial monitoring, diagnostics, and benchmarks in a centralized, holistic view to gain increased agility and understanding to improve operations and intervention strategies.

CASE STUDY

Rescuing a Critical Phase 3 Trial

CHALLENGE

A strategic trial is drastically underperforming in enrollment and the sponsor is requiring its CRO to provide deeper insights – down to the site level – in order to identify the issue and get the trial back on track.

APPROACH

Intelligent Trials data and capabilities were leveraged to compare their study performance against other similar studies and changing industry conditions down to the site level.

This enabled the sponsor and CRO to diagnose causes of slow enrollment, reduce protocol complexity, better segment sites, and develop a strategic intervention plan to accelerate the trial.

INTELLIGENT TRIALS | INSIGHT ADVANTAGE

Real time monitoring of a client's study against other similar trials to diagnose reasons for slow enrollment:

- Benchmarking study complexity, site, and patient burden
- Analysis of whether sites in study are enrolling similar patients for other trials

Deploy analytics taking into account past performance, competitive footprint, and experience with experimental treatments to segment sites and target interventions. Sites were segmented into categories:

- Current sites enrolling well for others and had high potential with intervention
- Current sites enrolling poorly across trials and had low potential (not a focus for intervention)
- New sites that had high potential given past experience and competitive footprint

IMPACT

- **6+ months trending study acceleration**
- **Immediate identification of sites requiring intervention**

4 CENTRALIZED STATISTICAL MONITORING

How do you identify and efficiently prioritize and remediate risks?

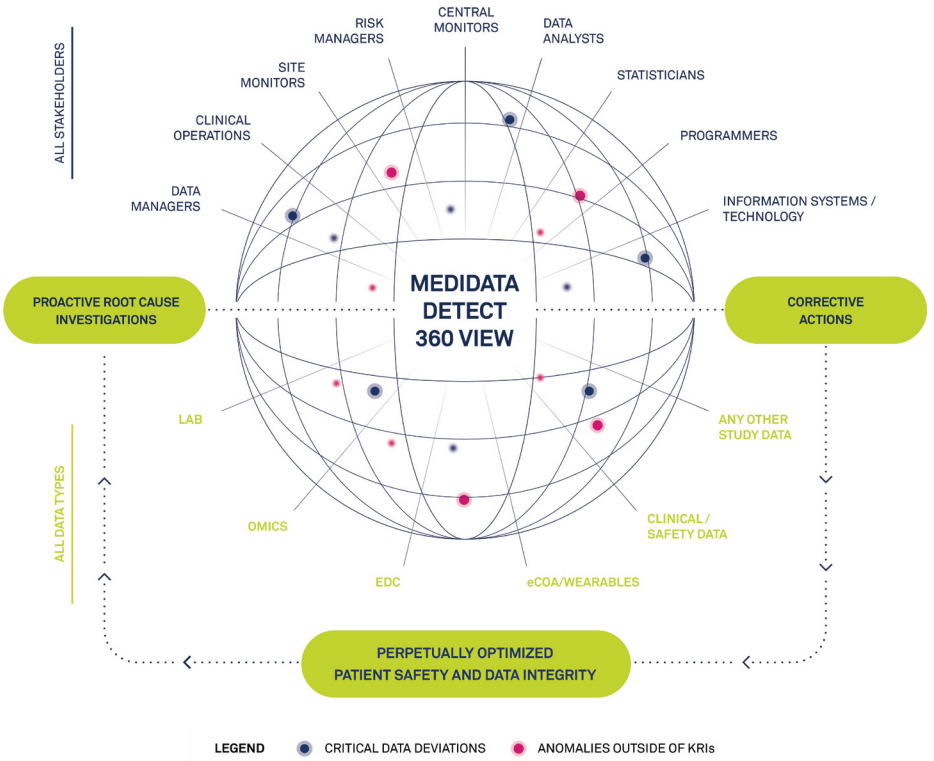
How important is it to detect and remediate errors, trends, and anomalies proactively in your trial?

Twenty four percent of study applications require one or more resubmissions before approval. A first unsuccessful submission can delay approval by a median of 435 days.[1]

Core to reducing trial risk and adopting a risk-based quality management (RBQM) approach is the ability to operationalize and oversee data integrity in a risk-based manner.

Medidata Detect simplifies the detection of errors, trends, and anomalies in study data through automated statistical algorithms and tests to improve study data quality and ensure patient safety.

Driven by machine learning and automated algorithms, Detect ingests and unifies study data. Data flows in real time and can be refreshed on demand, supporting the dynamic requirements for safety and quality review.



1. Sacks LV, Shamsuddin HH, Yasinskaya YI, Bouri K , Lanthier ML, Sherman RE, "Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000-2012." JAMA.2014;311(4):378–384. doi:10.1001/jama.2013.282542

THE IMMEDIATE IMPACT OF MEDIDATA DETECT

20%-40%
reduction in number of edit checks

50%-55%
of data reviews automated

83%
reduction in case review time by medical monitors

5 days
vs. ~4 weeks from LPLV to Database Lock for critical studies

Perpetually surveying millions of data points, Detect improves data integrity and reduces trial risk by delivering the visibility required to proactively perform root cause investigations and take corrective actions.

> Medidata Detect delivers cross-functional insight into reviewing the data. Our project managers get in and look at Detect prior to CRA's going out for their visit.
>
> They can look at their patients and their sites before the CRA ever arrives at the site. They have identified issues before they even open up that patient's chart.
>
> **— Director, Central Monitoring, Biotech Company**

BENEFITS INCLUDE:

Oversight

Automate flagging of data anomalies

Reduce risk of undetected anomalies

Compute KRIs and provide early indication of clinically significant trends

Efficiency

50%-55% of data reviews automated

20%-40% reduction in number of edit checks

Data Quality

Identify indications of potential misconduct

Reduce risks of submission delays by submitting cleaner data

Simplification

Reduction from 30 days to 5 days for database lock in critical studies

One central system for multiple review outputs (patient profiles, outlier detection, listings, KRIs, etc.)

MEDIDATA PARTNER PROGRAM

WHY 9 0F THE TOP 10 CRO PARTNERS TRUST MEDIDATA

At a time when investment resources are at risk post-COVID, CROs are tasked with accelerating development of treatments and devices, driving fast approvals, and generating data that will stand up to regulatory scrutiny.

Our fundamental values determine how we work and how we serve our customers. Trust is built and earned through years of commitment, accomplishment, and ethical behavior.

With over 20 years of experience, Medidata offers the only battle tested, end-to-end life science technology platform. Work across vendors, and leverage a unified solution with a single point of access and centralized near-real-time reporting to attract and win more sponsor bids.

By partnering with Medidata, CROs are able to not only attract and win more sponsor bids, but also execute them successfully.

THE FACTS

9 out of Top 10 CRO Partners

90 Medidata Accredited Parters with 280 Accreditations

900K+ Site/Sponsor Relationships

180+ Global Medidata Partners

7M+ Patients

GAIN A COMPETITIVE ADVANTAGE

> We're excited to be part of the early engagement program with Medidata on [the new myMedidata platform]. I think it's really exciting and it's going to benefit lots of patients.

parexel

> Through our partnership with Medidata, Medpace is now able to provide seamless integration of our quantitative image analysis pipelines with Medidata's Rave Imaging system and database.

MEDPACE

> Over the last 6 years, we have implemented over 130 studies in Rave RTSM and this number is growing every week. This is our standard approach that we configured.

Syneos Health

Learn the advantages to partnering with Medidata

DATA IS THE FUTURE OF CLINICAL TRIALS

CRO EDITION

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 1,800+ customers and partners access the world's most trusted 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**.

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