

# Intelligent Trials: Industry-leading data and advanced analytics for trial design, feasibility, and monitoring

## Overview

With 57% of trial protocols having at least one significant amendment resulting in delays and 90% of all trials worldwide not being able to find and enroll patients within their target timeframes, improving the design and operational setup of trials is critical to bringing drugs to patients faster and reducing costs. Although data and analytics hold the promise of helping to improve clinical operations, the availability of robust performance data, integration of multiple data sources, and ability to generate forward-looking insights can be key limiters for many organizations.

### ENTER INTELLIGENT TRIALS

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.

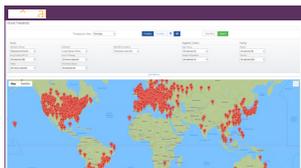
In addition, our expert driven trial optimization service leverages our data and capabilities and includes custom data integration, analytics, and decision support to address specific customer needs around trial planning, acceleration, and rescue.

Intelligent Trials' unique performance data and advanced analytics enhance decision-making across the clinical trial life cycle



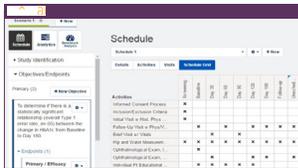
### IDENTIFY TARGET PATIENT POPULATIONS

- Use RWD to understand patient populations and impact of inclusion / exclusion criteria
- Link to operational design and required site characteristics to support site selection



### ACCELERATE ENROLLMENT

- Identify optimal countries and sites balancing speed, cost, and quality
- Predict enrollment at site, country, and trial level



### OPTIMIZE DESIGN

- Measure and benchmark site burden and patient burden
- Optimize protocol to balance scientific needs and operational efficiency



### MONITOR PERFORMANCE

- Focus effort to improve operations with a centralized view across all your trials
- Real time tracking of performance for your studies and sites against industry benchmarks and other active studies

## Industry Leading Performance Data

### Operational data

- 20,000 clinical trials, 5 million patients, and 22,000 healthcare facilities from across 94 countries
- Understand site performance including enrollment, study conduct, data quality, and competitive landscape

### Protocol and cost data

- 30 thousand protocols and 2.4 million negotiated line item payments
- Quantitatively measure and benchmark site burden, patient burden, and cost of your trial

### Linked external data

- Accelerators to ingest and integrate publicly available, 3rd party, real-world (EMR, claims), and client data
- Enrich data, define patient populations, and create single view of attributes

For more information, go to [acornai.com](https://acornai.com)

Questions? Email us at [contact-us@acornai.com](mailto:contact-us@acornai.com)

## Case Example: A pharma company seeks to enter a rare disease area

### THE CHALLENGE

A pharma company identified a promising novel therapy for a rare disease but didn't have the experience in the TA to develop a best-in-class clinical development program. Data availability was a challenge given fewer than 20 trials had been run in the disease.

### APPROACH

Closely collaborating with client's data scientists, an Intelligent Trials team integrated multiple data sets for the rare disease and related indications across Medidata's trial data, clinicaltrials.gov, PubMed, ensus and the client's data. Tailored analytics helped identify attractive sites and prioritize based on past performance, competitive trial congestion, patient population and KOLs.

Site ID	Site Name	Site City	Site State	Site Experience in Indication	Active Trials	Enrollment Trending	Accession Score	Patient Population Score	Regulatory Present
1941	✓ Emory Healthcare - Emory University Hospital	Atlanta	GA	2	2	High	67%	12%	
1549	✓ University of Miami Hospital	Miami	FL	6	6	High	157%	8%	Dr. XXX
19581	✓ The University of Chicago Medicine	Chicago	IL	1	2	High	119%	6%	
31785	✓ NewYork-Presbyterian / Columbia University Medical Center	New York	NY	6	8	Med	99%	6%	Dr. XXX
572	✓ Penn Medicine - Hospital of the University of Pennsylvania	Philadelphia	PA	2	3	Med	117%	8%	Dr. XXX
1301	? University of Kansas Medical Center	Kansas City	KS	3	4	Med	441%	5%	Dr. XXX
28767	? Northwest Louisiana Nephrology	Shreveport	LA	4	5	High	1042%	14%	
21906	✗ Coastal Nephrology Associates	Port Charlotte	FL	1	2	Med	1492%	3%	
115444	✗ La Jolla Clinical Research, Inc	San Diego	CA	1	1	Unknown	32%	2%	
115440	✗ Phoenixian Centers for Research & Innovation (PCRI)	Phoenix	AZ	1	2	Low	125%	2%	

Prioritized site and investigator list based on multiple criteria

### IMPACT

Insights generated enabled the client to develop a robust strategy for their clinical development program in an indication new to them.

## Case example: A top pharma looking to accelerate a trial with enrollment challenges

### THE CHALLENGE

A top pharma company's trial in a highly competitive space had been open for close to a year but was struggling to enroll patients. They were trying to rapidly identify the root causes and take action to accelerate enrollment.

### APPROACH

An Intelligent Trials team ran site-level diagnostics to understand site performance compared to competitive trials and characteristics of over and underperforming sites. A protocol assessment was performed to quantify complexity and patient burden relative to indication benchmarks. The client's country footprint was assessed to identify additional countries to consider for the trial. Finally, a predictive model was deployed to identify a set of sites and investigators with higher expected enrollment performance given the trial characteristics and the competitive landscape.

### IMPACT

Key findings included client's protocol being overly complex, capacity issues at sites selected due to a recent and significant jump in number of competing trials and sites not experienced in delivering trials with the specific characteristics of the client's trial.

Armed with these insights, the client amended their protocol to reduce site and patient burden. Predictive modeling identified 2 new countries and a priority set of sites to add to the trial. Lastly, a new study design and monitoring approach is being put in place to support future trials.

## Industry leaders committed to shaping the future of life sciences

Our integrated team of industry experts, data scientists, technologists, and ex-regulatory officials bring deep expertise to frame the right questions and extract answers to support your most important questions.

## About AcornAI

Acorn AI™ is a Medidata company that represents the next horizon of the industry leader's 20-year mission of powering smarter treatments and healthier people. Acorn AI is designed to make data liquid across the entire lifecycle and to answer the most important questions in R&D and commercialization for customers. Built upon the Medidata platform comprising more than 20,000 trials and 5 million patients, Acorn AI products feature one of the industry's largest structured, standardized clinical trial data repository connected with real world, translational and other datasets. For more information:

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