

# Medidata Acorn AI - Propelling the Innovators

## Rethinking The Limits of Human Data Science

Medidata Acorn AI provides unparalleled clinical data, advanced analytics and industry expertise for pharmaceutical, biotech and medical device leaders, to help reimagine what is possible, uncover the breakthrough insights, make confident decisions and pursue continuous innovation from R&D to commercial launch.

We have developed clinical trial solutions that were completely unimaginable only a few short years ago, transforming not only the way clinical trials begin, but how they end, and at every stage in between. Our suite of solutions is backed by an integrated team of scientists, physicians, technologists, and ex-regulatory officials who bring deep expertise to frame the right questions and extract answers to support your most important questions.

## Solutions

Acorn AI is built upon Medidata's core platform comprising 23,000 trials and nearly 7 million patients. It features the industry's largest and most complete historical clinical trial data repository that includes more than 45 billion data points. What makes Medidata's data unique is patient-level data pulled directly from all case report forms from trials. We capture 100+ individual-level clinical fields and 35+ operational covariates.

### Intelligent Trials

Gain a competitive edge in trial planning, site selection, and enrollment. Improve the speed, quality and success of clinical trials by optimizing protocol design, leveraging predictive models for enrollment and site selection, and tracking of ongoing trial and portfolio performance against industry in real time, all driven by real-time, cross-industry clinical trial data.

### Synthetic Control Arm®

Build regulatory-grade patient-level matched control arm using rigorous, biostatistical-driven methods based on patients from previous clinical trials. Use case includes enhanced interpretation of single arm studies, breakthrough therapy designation, and support for value discussions with payers and health authorities.

### Trial Design And Disease Insights

Validate appropriate clinical endpoints and see patient cohorts in experimental vs. launched therapies by intelligently combining historical clinical trial and real world data. Identify usage patterns with respect to different patient demographics, comorbidities and risk profiles in real world and clinical trial settings.

## Solutions Continued...

### Connected Patient

Develop personalized treatments by tapping into the broad digital ecosystem around the patient. Example use cases: pre-surgical planning, undiagnosed/under-diagnosed patients, digital surgery, tumor board mgmt, custom device manufacturing.

### Commercial Data Solutions

Accelerate launch to peak by leveraging our 15+ year history in commercial data management. As companies plan and execute on their launch strategies, they require trusted partners that can deliver technology, expert resources and insights that enable success at all phases of the commercial drug lifecycle.

## The Medidata Acorn AI Advantage

From planning to launch, we are your collaborative partner -- pushing the innovations realized through unparalleled clinical trial data, deep industry and human expertise, advanced analytics and predictive modeling. Acorn AI is dedicated to ensuring that new possibilities are always on the horizon ... for you, the patients we ultimately serve, and life sciences as a whole.

*"We are extremely impressed with the Acorn AI team for providing a scientifically rigorous rationale for the design of an innovative registration trial incorporating an external control arm for the treatment of recurrent glioblastoma (rGBM) with MDNA55. Their expertise and collaborative effort with thought leaders was instrumental in demonstrating to the FDA the validity of a well designed external control in a registration trial. The FDA's acceptance of this unique design will expedite completion of the Phase 3 trial in rGBM, allowing earlier access of MDNA55 for a disease with poor prognosis and high unmet need."*

**- Fahar Merchant, PhD, President and CEO, Medicenna Therapeutics, Corp.**

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