Increase the Probability of Regulatory and Technical Success

WHICH POPULATIONS SHOULD WE STUDY?

WHICH ENDPOINTS SHOULD WE SELECT?

WHAT COMPARATOR SHOULD WE CHOOSE?

HOW CAN WE BE MORE CERTAIN ABOUT OUR CHOICES?

SHOULD WE ADVANCE TO THE NEXT PHASE OR TERMINATE?

HOW ELSE CAN WE STRENGTHEN THE EVIDENCE TO SUPPORT REGULATORY APPROVAL AND DEMONSTRATE THE PRODUCT VALUE?

Today's clinical trials are becoming increasingly complex — with rising costs, a faster evolving treatment landscape and a growing risk of trial failure. To mitigate this uncertain landscape and make better data-driven decisions, clinical development groups have turned towards real world data (RWD) to augment and inform their understanding of the disease and treatment landscape.

The clinical development process for medical therapies has multiple aims, including

- To produce the strongest possible scientific case for the efficacy & safety of the new treatment relative to a placebo or the standard-of-care to support approval by regulatory agencies

- To make the strongest case to physicians, patients and payors for the value of the new treatment relative to the current standard of care

However, the challenge of finding and matching the right data to a development program means many decisions must be made without the strong supporting evidence that a clinical developer would desire.

Integrated Evidence from Acorn AI provides access to a one of a kind cross-sponsor, regulatory grade, patient-level clinical trial dataset with pre-integrated real world assets to help clinical developers make critical data-driven decisions throughout the product development lifecycle and increase their probability of success.

Access to an unmatched Clinical Trial database linked with Real-world Evidence powers insight-led Clinical Program Design

22,000
Clinical Trials

6,000
Clinical Trials Ongoing

6M
Trial Patients

94
Countries

22,000+
Healthcare Facilities

45B+
Data Points

300+
RWD Adaptors

1,000+
EMR and PACS Connections for live feed

1.5B+
Medical Images

For more information, go to acornai.com

Questions? Email us at contact-us@acornai.com
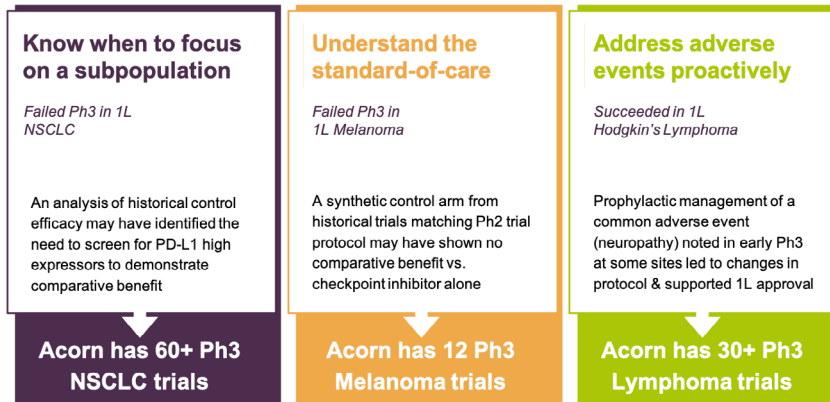
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INCREASE YOUR PROBABILITY OF SUCCESS:

Despite thousands of trials with clinical data that could inform future development programs, failure is still common

	Completed Trials	Ongoing Trials	Success Rate
Oncology	9,251 **3,700+** since first PD-1 inhibitor in 2015	3,410	35%
Inflam/Immuno	8,380 **7,000+** since first biologics approved c. 2000	859	35%
Cardiovascular	4,306	420	30%
Infectious disease	5,527	671	35%
CNS	8,239	771	33%
Rare/ Metabolic	6,417	603	35%

Trial count includes Phase 2 and Phase 3 industry trials only.
Success is defined as meeting the primary endpoint
Source: Informa / TrialTrove.

The right data may stand between success and failure

Know when to focus on a subpopulation

Failed Ph3 in 1L NSCLC

An analysis of historical control efficacy may have identified the need to screen for PD-L1 high expressors to demonstrate comparative benefit

Acorn has 60+ Ph3 NSCLC trials

Understand the standard-of-care

Failed Ph3 in 1L Melanoma

A synthetic control arm from historical trials matching Ph2 trial protocol may have shown no comparative benefit vs. checkpoint inhibitor alone

Acorn has 12 Ph3 Melanoma trials

Address adverse events proactively

Succeeded in 1L Hodgkin's Lymphoma

Prophylactic management of a common adverse event (neuropathy) noted in early Ph3 at some sites led to changes in protocol & supported 1L approval

Acorn has 30+ Ph3 Lymphoma trials

Offering data for:

Oncology

- Breast Cancer
- Leukemia
- Melanoma
- Multiple Myeloma
- Myelodysplastic Syndrome
- Non-Hodgkin's Lymphoma
- Non-Small Cell Lung Cancer
- Prostate Cancer

Non-oncology

- Alzheimer's Disease
- Atopic Dermatitis
- Hypertension
- Parkinson's Disease
- Psoriasis
- Rheumatoid arthritis
- Schizophrenia
- Stroke

*additional indications coming soon

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DRIVE IMPACT IN CLINICAL DEVELOPMENT

Function	Clinical Development
Impact	• **Increase the probability of regulatory success** • **Decrease trial costs** e.g., power shorter, smaller trials, capture effects sooner, supplement registration data
Insights Examples	• Identify target populations • Select controls or comparators • Assess risk:benefit • Inform Go vs. No-Go decisions
Platform	**CLINICAL TRIAL DATA + REAL WORLD DATA + ANALYTICS + TECHNOLOGY TO** • **Deliver Insights** e.g., research reports and white-glove service to answer highest impact questions • **Enable exploration and discovery** e.g., cloud-backed workbench and dashboards

ACORN AI DELIVERS SOLUTIONS THROUGH OUR QUANTUM PLATFORM

Supports analysis of Clinical and Real-World data for Acorn analysts, pharmaco customers and third-party analysts

Potential Value

$200-300M
from increased probability of success from Ph 2 - Ph 3

$400-600M
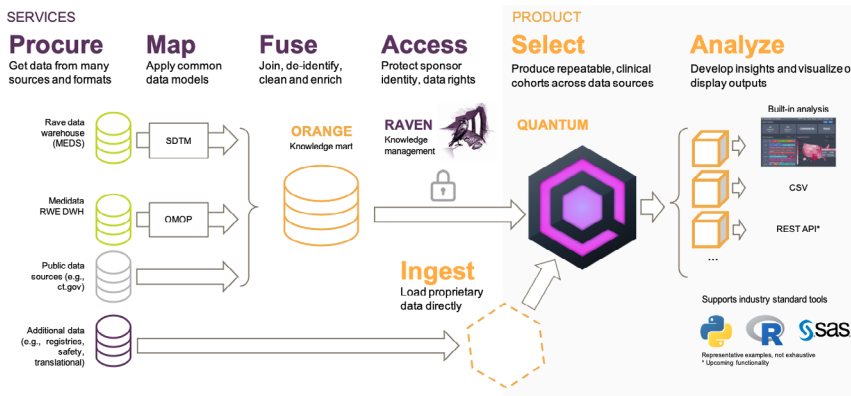higher commercial value

$4-60M
lower trial costs

$0.6 -1B
total potential value from optimal decision-making Ph1 - Launch

May be lower depending on phase or TA

About AcornAI

Acorn AI™, by Medidata, a Dassault Systèmes company, combines data, technology, and deep expertise to help life sciences companies deliver actionable insights across the entire continuum of clinical development. Acorn AI's advanced analytics answers the most important questions in R&D and commercialization including accelerating breakthrough innovation, optimizing study execution and commercial success, and demonstrating the value of therapies. Built upon the Medidata platform comprising 20,000+ trials and more than six million patients, Acorn AI products feature the industry's largest structured, standardized clinical trial data repository connected with real world, translational, and other datasets. For more information, please visit

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