Increase the Probability of Regulatory and Technical Success

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

Copyright 2020 Medidata Solutions, Inc., a Dassault Systèmes company
INCREASE YOUR PROBABILITY OF SUCCESS:

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Completed Trials</th>
<th>Ongoing Trials</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology</td>
<td>9,251</td>
<td>3,410</td>
<td>35%</td>
</tr>
<tr>
<td>Inflam/Immuno</td>
<td>8,380</td>
<td>859</td>
<td>35%</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>4,306</td>
<td>420</td>
<td>30%</td>
</tr>
<tr>
<td>Infectious</td>
<td>5,527</td>
<td>671</td>
<td>35%</td>
</tr>
<tr>
<td>CNS</td>
<td>8,239</td>
<td>771</td>
<td>33%</td>
</tr>
<tr>
<td>Rare/</td>
<td>6,417</td>
<td>603</td>
<td>35%</td>
</tr>
</tbody>
</table>

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 Phase 3 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

- **Understand the standard-of-care**
  - Failed Phase 3 in 1L Melanoma
  - A synthetic control arm from historical trials matching Phase 2 trial protocol may have shown no comparative benefit vs. checkpoint inhibitor alone

- **Address adverse events proactively**
  - Succeeded in 1L Hodgkin’s Lymphoma
  - Prophylactic management of a common adverse event (neuropathy) noted in early Phase 3 at some sites led to changes in protocol & supported 1L approval

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*
DRIVE IMPACT IN CLINICAL DEVELOPMENT

<table>
<thead>
<tr>
<th>Function</th>
<th>Clinical Development</th>
</tr>
</thead>
</table>
| Impact   | • Increase the probability of regulatory success  
           • Decrease trial costs  
           e.g., power shorter, smaller trials, capture effects sooner,  
           supplement registration data |
| Insights | • 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 |

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 www.medidata.com/acornai  
contact-us@acornai.com  
+1 866 515 6044