

# JP Morgan Healthcare Conference 2022

# Introductions



**Sastry Chilukuri**  
Co-CEO, Medidata  
Founder, President, Acorn AI



**Arnaub Chatterjee**  
SVP, Acorn AI

# Executive Summary

- The Life Science industry is unlocking new frontiers in speed and complexity of therapeutic innovation. Technology, Patient Engagement, AI and Data platforms are critical to accelerate these therapies to patients. Capital markets are backing these trends with significant investments
- We are the industry leader with 7,000+ ongoing clinical trials with world leading sponsors and partners. Our multi-year investments in areas such as Patient Centricity and Data and AI are paying off
- This establishes the foundation for our accelerated growth. Our next-gen life science cloud platform brings real-time AI and rich customer engagement to the point of use and closes the loop across Research & Discovery, Development, Manufacturing and Commercial
- Our focus for 2022 and beyond remains on helping the industry (biopharma, med tech, diagnostics) bring new therapies to patients faster, attract the best talent in healthtech and continue to drive innovation in this import space

# Transform How Therapies Get to Patients



+



**= Accelerate and  
de-risk therapeutics  
for patients**

# Our Mission

## Power Smarter Treatments and Healthier People

**#1**

MS in LS<sup>1</sup>

**\$8B**

of TAM<sup>2</sup>

**17 of Top 20**

Selling Drugs Developed  
on MEDIDATA in 2020

**8,000+**

Customers

**20 of 20**

Top Biopharma,  
CRO and Medtech

**75%**

Of Oncology Approvals  
Supported 2015 - 2021

<sup>1</sup> Dassault Systèmes + Partners' WW Life Sciences & Healthcare products total software market + IDC 2019 SW vendors' revenue

<sup>2</sup>Total Addressable Market; sources: Dassault Systèmes' internal sources + Industry analysts' studies from ARC Advisory Group and IDC

## Financial Metrics

**13-15%**

y/y revenue growth

**200bps**

y/y margin improvement

**Growing Operating Cash Flow**

in line with operating margin expansion

## Growth Levers



Winning **market share** in core market: Rave and Attach



Connecting to **Patients & Healthcare ecosystem**



Data, Analytics and AI enable **unique insights and actions**



Optimizing **resource allocation and synergies** across the company



**End to end platform** for Life Sciences creating new business opportunities

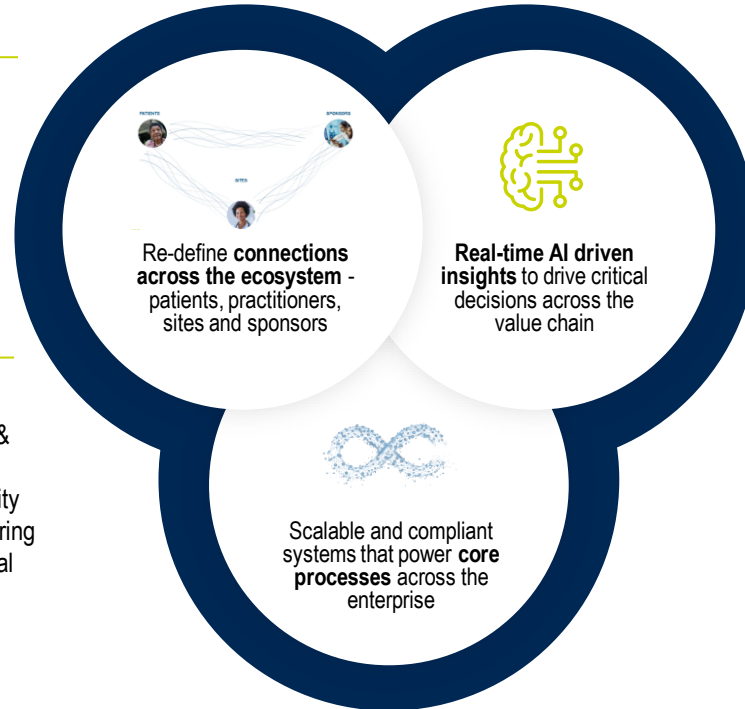
# Our Life Sciences Cloud Platform Drives Real-Time AI and User Engagement

## Vibrant Ecosystem

- 8,000 customers and partners
- 7.8M+ patients
- 95,000+ physicians
- 30,000+ facilities
- 145+ countries

## Critical Functions

- Study Conduct
- Clinical Operations & Decentralized Trials
- Evidence Generation
- Patient Engagement
- Research & Discovery
- Total Quality
- Manufacturing
- Commercial Launch



## Award Winning AI Powered By Unique Data

- ~26,000 trials
- 7,500+ live studies
- 1B images in 2021



# Platform

## Partnering on the COVID-19 Vaccine Program

**moderna™**  
messenger therapeutics

mRNA Therapeutic Vaccine  
Phase 3: 30,000 participants, 98 sites, 28M data points, 5 months

**NEXT**

**Laurie Callen**  
Senior Director, Clinical Data Management  
Moderna

**Melanie Ivarsson, PhD**  
Chief Research Officer  
Moderna

**Keith Nix**  
Chief, Site Partnering

**Glen de Vries**  
Senior Director, Clinical Data Management  
Moderna

**Marcello Damiani**  
PhD, Director of Operations  
Moderna

#MedidataNEXT

**NEXT** Life Sciences Series

**Hybrid decentralized approach to study execution**

**Real-time use of AI to identify sites, patients and data quality issues**

**30,000+ patients provide sensor and outcome data**

**Workflow innovation to realize unprecedented speed and compliance**

**Breakthrough use of RWE for long-term follow-up**

Sources: <https://www.medidata.com/en/press-releases/medidata-supports-moderna-covid-19-vaccine-clinical-trials-with-rwe-clinical-cloud-platform>  
<https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>  
<https://www.statista.com/statistics/1198516/covid-19-vaccinations-administered-us-by-company/>

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# Platform

## Closing the Loop to Enable Bedside-Bench-Bedside Therapies

### 1. Collection



### 2. Testing



### 3. Processing



### 4. Medicine



### 5. Treatment



Donor  
Management



Plasma Supply  
Optimization



Lab  
Testing



Process  
Simulation



Process  
Execution



Process  
Monitoring



Medicinal  
Product



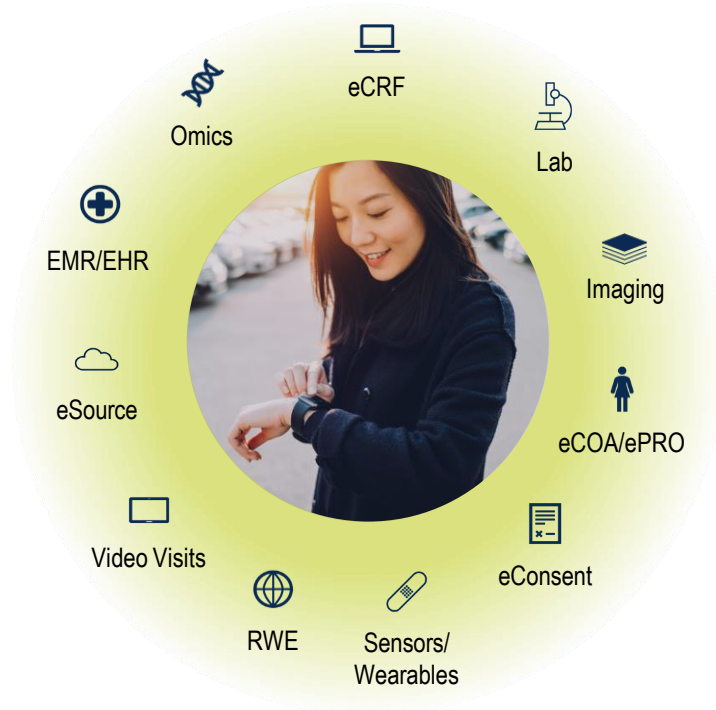
Product Supply  
Optimization



Post-market  
Monitoring

# Study Conduct

## Rave EDC Goes Beyond eCRF



### Scale

- 4,500+ Study starts in 2021
- World-class privacy, security, compliance and quality

### Growing Complexity

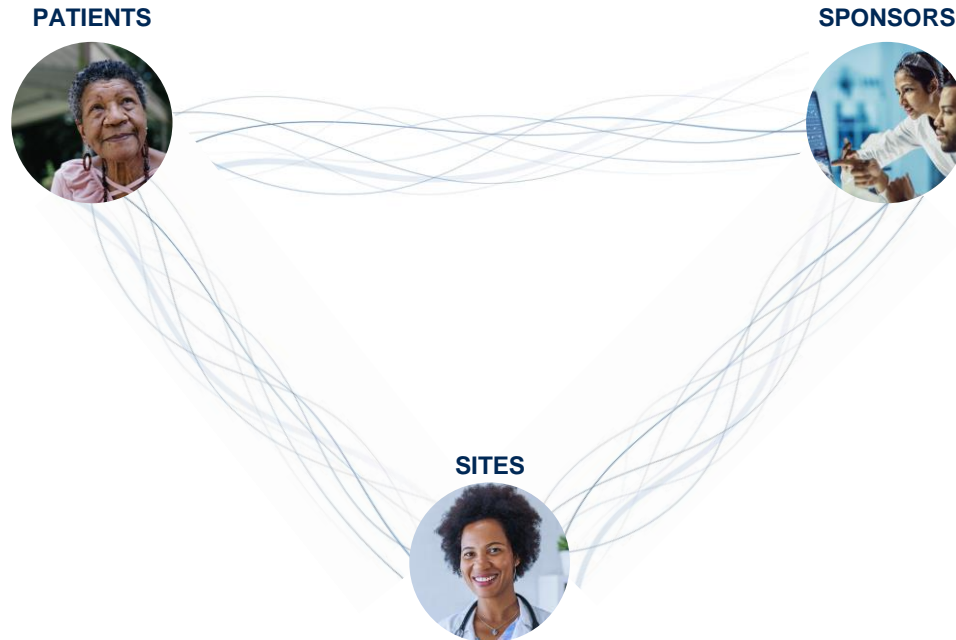
- Streaming data
- ePRO, eCOA
- Video visits
- Tokenization

### Innovation

- Intelligent workflows - Interim study lock/data cut, mid-study change process, **eSource**
- Autonomous of **Medical Coding**
- Integration - Supply forecasting with **RTSM**

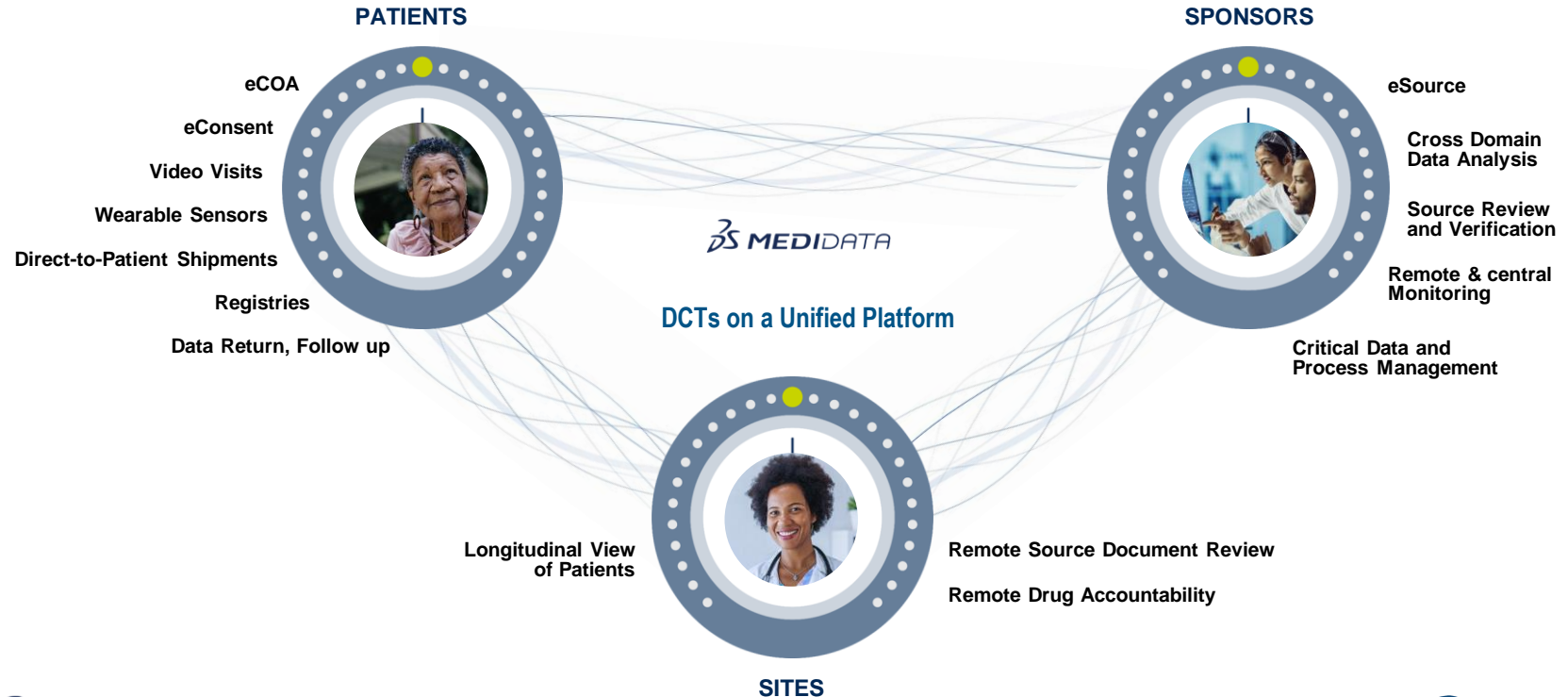
# Clinical Operations & Decentralized Trials

## COVID-19 Has Permanently Changed the Interactions Between Sponsors, Sites, and Patients



# Clinical Operations & Decentralized Trials

## Our Platform Orchestrates Complex Interdependencies...



# Clinical Operations & Decentralized Trials ...Powered With Live Analytics...

PATIENTS



SPONSORS



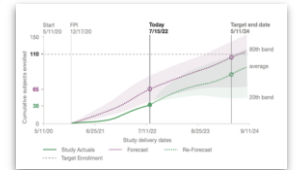
Central Cockpit



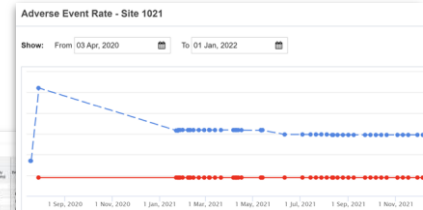
Patient Activity



Real-Time Forecasting



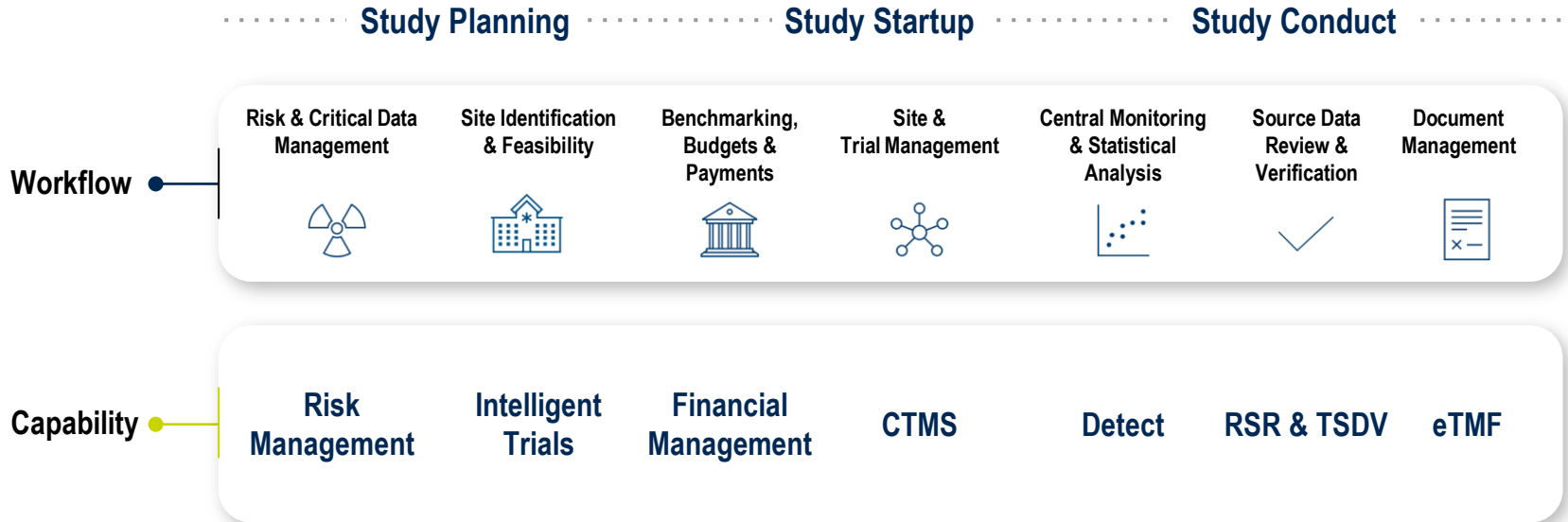
SITES



| Study       | Phase   | Country | Site      | Status |
|-------------|---------|---------|-----------|--------|
| SPONSOR-001 | Phase 1 | USA     | Site 1001 | Open   |
| SPONSOR-001 | Phase 1 | USA     | Site 1002 | Open   |
| SPONSOR-001 | Phase 1 | USA     | Site 1003 | Open   |
| SPONSOR-001 | Phase 1 | USA     | Site 1004 | Open   |
| SPONSOR-001 | Phase 1 | USA     | Site 1005 | Open   |
| SPONSOR-001 | Phase 1 | USA     | Site 1006 | Open   |
| SPONSOR-001 | Phase 1 | USA     | Site 1007 | Open   |
| SPONSOR-001 | Phase 1 | USA     | Site 1008 | Open   |
| SPONSOR-001 | Phase 1 | USA     | Site 1009 | Open   |
| SPONSOR-001 | Phase 1 | USA     | Site 1010 | Open   |

# Clinical Operations & Decentralized Trials

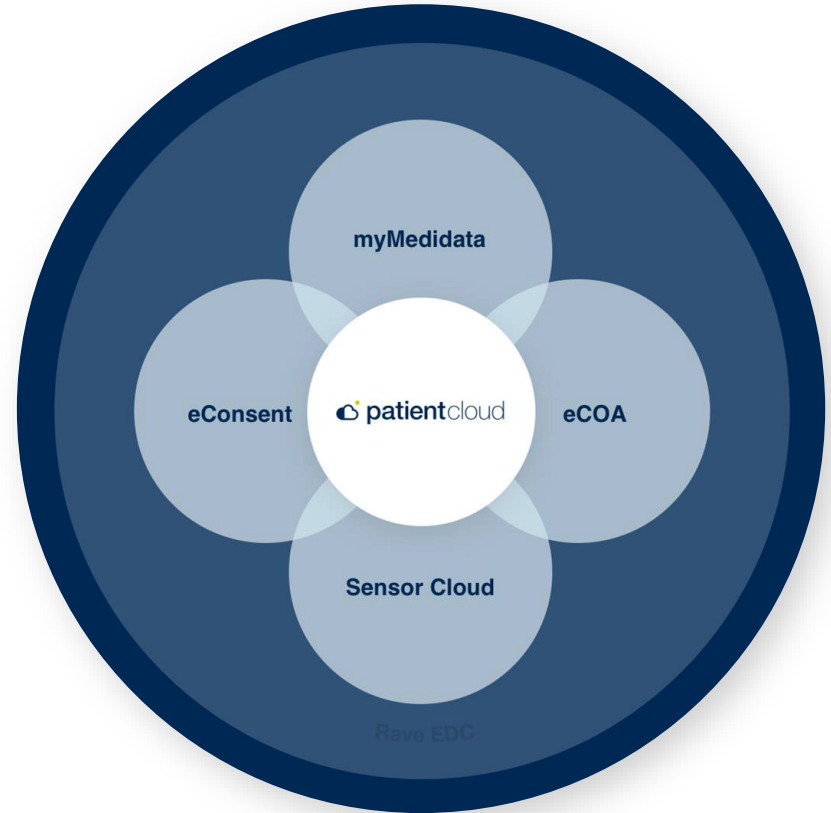
## ...Embedded Within Compliant Workflows



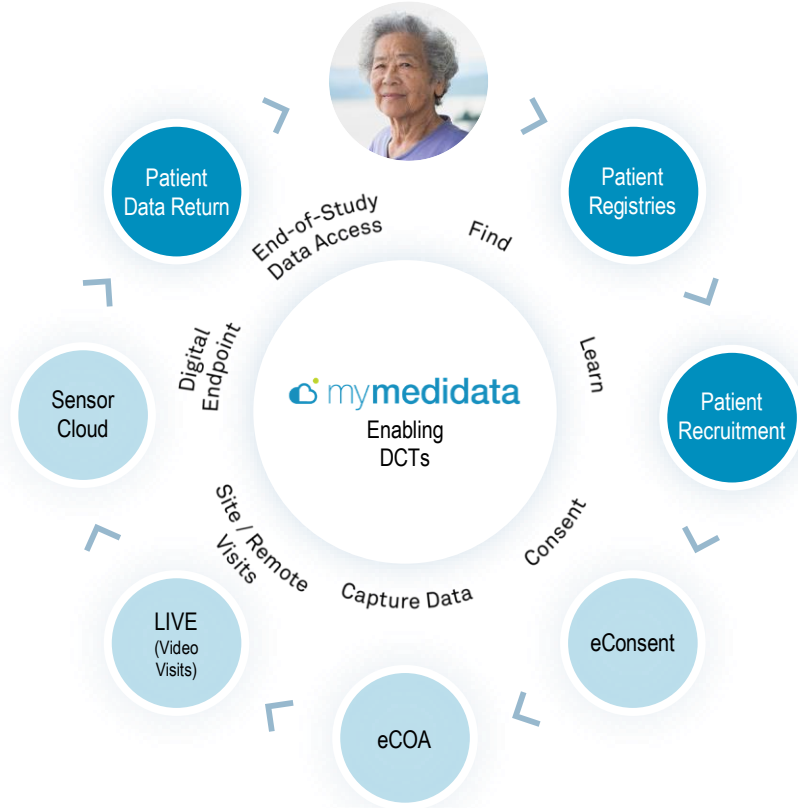
# Patient Engagement and Experience Medidata Patient Cloud

## A suite of patient-centric digital health solutions focused on:

- Enabling greater patient participation in clinical research
- Breaking down the barriers of traditional clinical trials through a single, unified platform
- Empowering patients to share data on their terms regardless of location



# Patient Engagement and Experience myMedidata

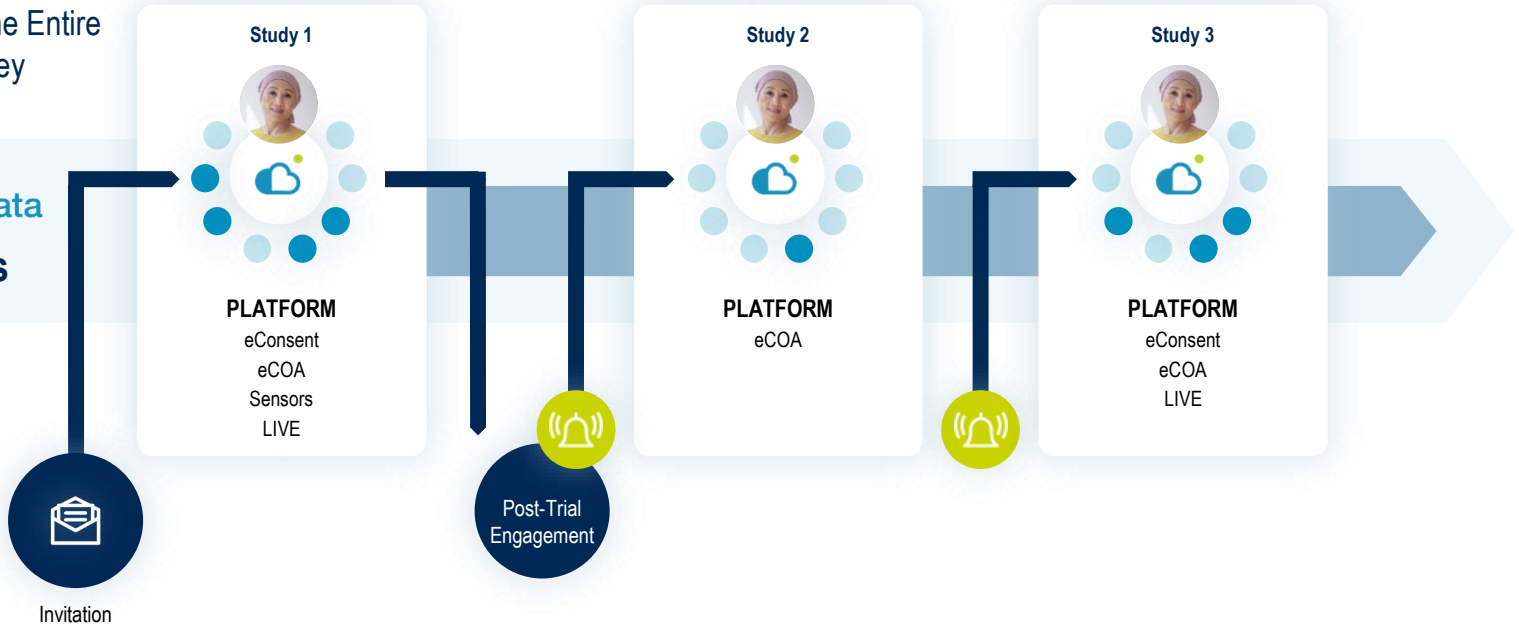




# Patient Engagement and Experience Single Clinical Trial Dashboard

Throughout the Entire  
Patient Journey

  
**Registries**



Invitation

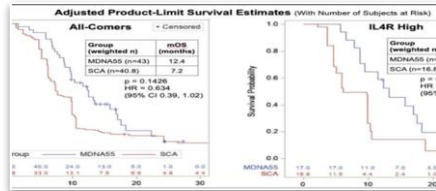
Post-Trial  
Engagement

# Evidence Generation

## Synthetic Control Arm

Augment or replace randomized controls with **historical trial data**

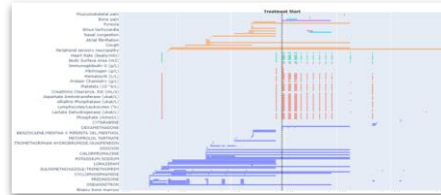
**Inform internal decision making and enhance interpretation** of single arm trials



## Trial Design

**Increase probability of success** with accurate selection of target population, comparator arm, and clinical endpoints

**AI-enabled predictive modeling** of outcomes



## Medidata Link

**Linking individual patients to their clinical trial and real-world data** to create a universal record

**Evaluate safety and efficacy** to inform market access and PV



# Evidence Generation

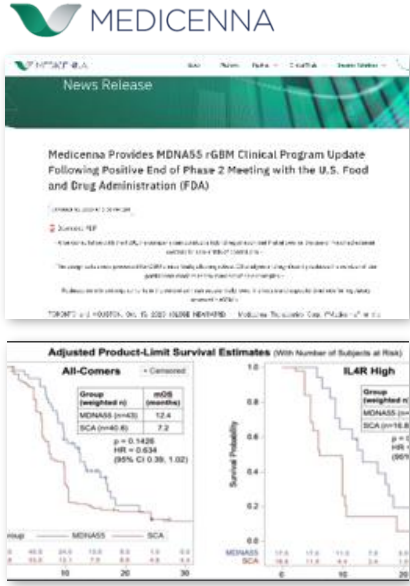
## Two Regulatory Approvals From FDA CDER and CBER in rGBM Using Synthetic Control Arms™

### Context

- Two clients in the recurrent glioblastoma space asked Acorn to build synthetic control arms for regulatory submission in phase 3 confirmatory trials
- Acorn designed the SCA, including phase III protocol and SAP and prepared the EoP2 briefing packet including justification of hybrid SCA to regulators and presented at FDA EoP2 meeting

### Results of Acorn Analysis

- Two separate FDA agencies (CDER and CBER) independently agreed to use of historical clinical trial data and hybrid SCA design in phase 3 confirmatory trial
- We were able to augment the trial by providing 100 “synthetic patients” in the control arm, reducing clinical development cycle by 6 months



The image shows a screenshot of a Medicenna news release titled "Medicenna Provides MDNA55 rGBM Clinical Program Update Following Positive End of Phase 2 Meeting with the U.S. Food and Drug Administration (FDA)". Below the text are two Kaplan-Meier survival plots. The left plot is for "All-Comers" and the right plot is for "IL4R High". Both plots compare the MDNA55 group (n=45) and the SCA group (n=100). The All-Comers plot shows a hazard ratio (HR) of 0.634 (95% CI 0.39, 1.02) with a p-value of 0.0428. The IL4R High plot shows a p-value of 0.0461 (95% CI).

“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.

**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.”**

**Dr. Fahar Merchant, President and CEO of Medicenna (October 15, 2020)**

[The full press release can be viewed here.](#)



# Research and Development Small Molecule and Biotherapeutics Design



**Precise Targeting**

Target Selection



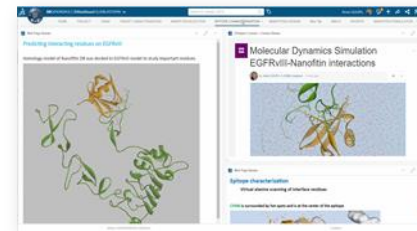
**50% Reduction  
in Cycle Times**

AI Driven Therapeutics Design



**20% Reduction  
in Cost & Time**

Biologies, Cell, & Gene  
Therapies Design

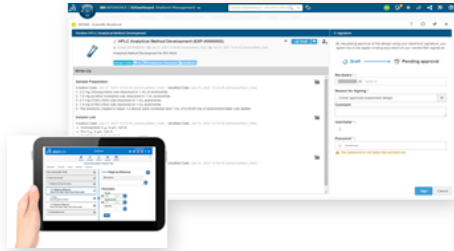


# Manufacturing CMC Development, Tech Transfer, Monitoring



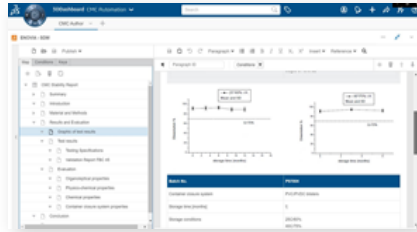
25% Boost in Lab  
Efficiency & Productivity

One Lab



30% Reduction  
in Tech Transfer Time

License to Cure



30% Reduction  
in Tech Transfer Time

Made to Cure



# Our Priorities



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Focus on helping customers  
bring therapies to patients  
faster



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Attract the best talent  
around our shared mission  
and culture



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Continue to innovate at the  
intersection of biology and  
tech, data and AI

