FROM LAB TO MANUFACTURING

Jason Benedict, BIOVIA CEO
Tom Doyle, MEDIDATA CTO

BIOPHARMACEUTICALS | BUSINESS DRIVERS

COMPLEXITY
Of new product classes

SPEED TO MARKET
Clinical & Manufacturing

PRECISION RELEASE
Same Day Release

COST PRESSURE

REGULATORY PRESSURE

SUSTAINABILITY
Mandate

BIOPHARMA | CURRENT CHALLENGES

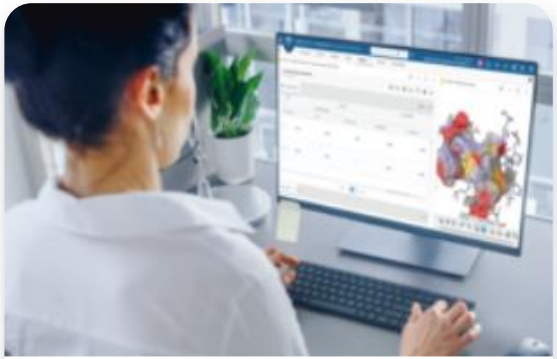
Drug Candidate — IND — NDA — APR

Develop

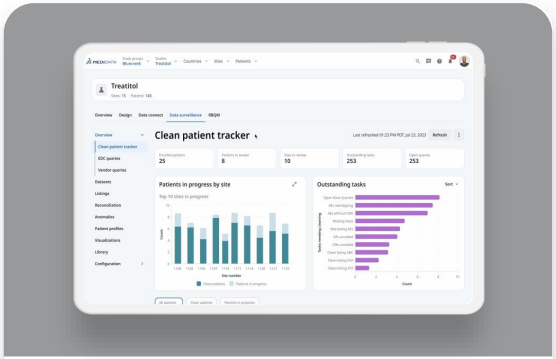
Research & Discovery | Preclinical | Clinical Development & Supply

Supply, Manufacture & Control

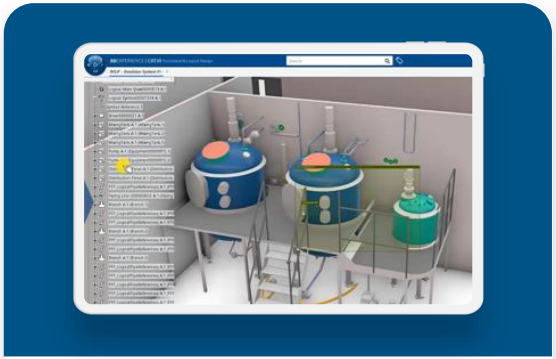
Phase 1 | Phase 2 | Phase 3 | Commercial Manufacturing



Faster to IND
Speed to Patient



Clinical Development
Patient Outcomes



Manufacturing
Right First Time & Efficient Release

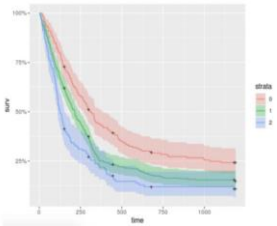
DASSAULT SYSTEMES

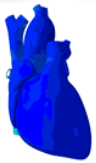
BIOPHARMA | VIRTUAL TWIN EXPERIENCES

Combine Real World Data with **Models** to Deliver **Outcomes**

Patient Virtual Twin

Clinical Trial | Cohort
Organ | Tissue

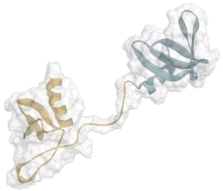




The Living Heart Project

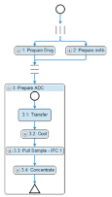
Product Virtual Twin

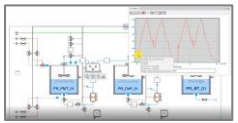
Molecule | Formulation
Device | System Architecture



Process Virtual Twin

Recipe | Method | Operations
Process Parameters | Controls





Plant Virtual Twin

Building | Environment
Equipment | Resources

Product fit for the Patient, Process fit for the Product, Plant fit for the Process

BIOPHARMA | LAB TO PLANT

Drug Candidate — IND — NDA — APR

Develop

Research & Discovery | Preclinical | Clinical Development & Supply

Supply, Manufacture & Control

Phase 1 | Phase 2 | Phase 3 | Commercial Manufacturing

Translational Science & Precision Medicine — Patient Journey & Real World Evidence Gathering

LAB Analytical Methods development & experiments

QC Lab — TECH TRANSFER — QC Methods management & execution — QC LAB — QC Lab

Document general recipe for NDA approval

Scheduling synchro | Samples logistic | Certificate of analysis

Document general recipe updates for APR

LAB Lab Recipe development & experiments

Pilot — TECH TRANSFER *pilot recipe scale up & execution* — Production Plant — Production Recipe management & execution — Plant

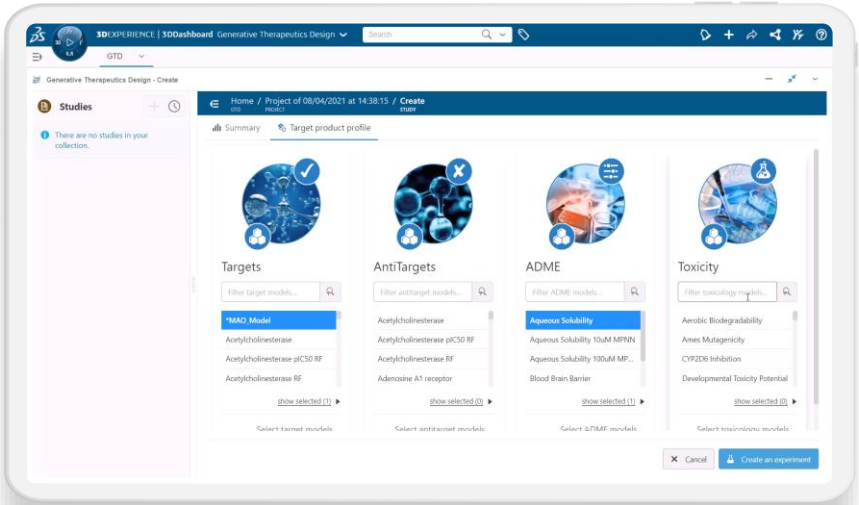
Internal or Partner (CDMO) — Internal or Partner (CDMO) — Inter plant transfers

CDMOs: Contract Development and Manufacturing Organizations

Enterprise Collaboration | Quality | Regulatory | Compliance | Knowledge Capitalization | .../...

BIOPHARMA | GENAI EXPERIENCES FOR DISCOVERY

Small Molecule | Biologics | Cell Therapies



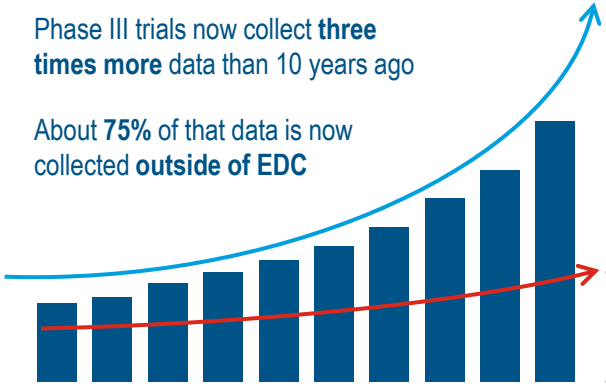
Leveraging advanced MODSIM + AI to Accelerate Cycle Times, Optimize Efficacy and Safety, and Improve Clinical Outcomes

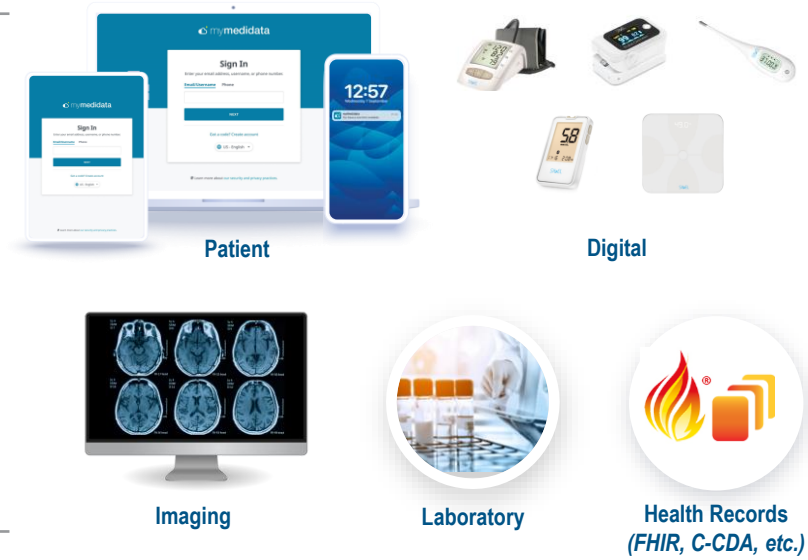
BIOPHARMA | CLINICAL ACCELERATION

Data Availability

Phase III trials now collect **three times more** data than 10 years ago

About **75%** of that data is now collected **outside of EDC**

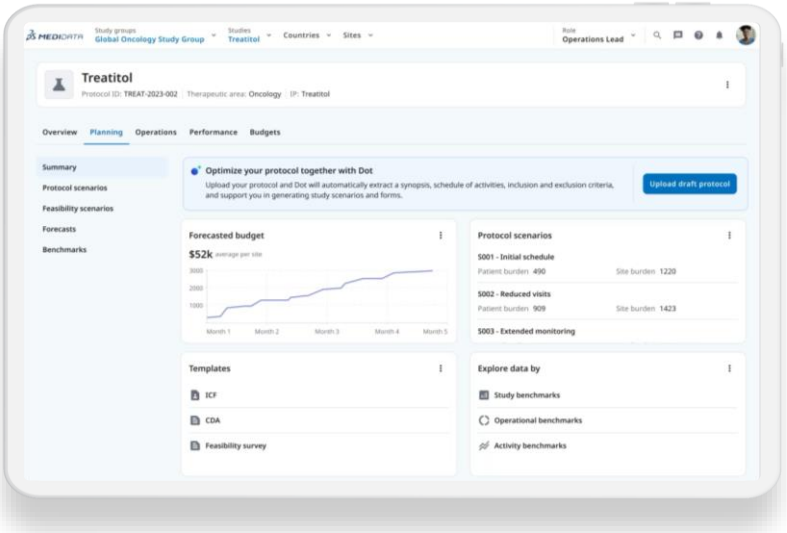


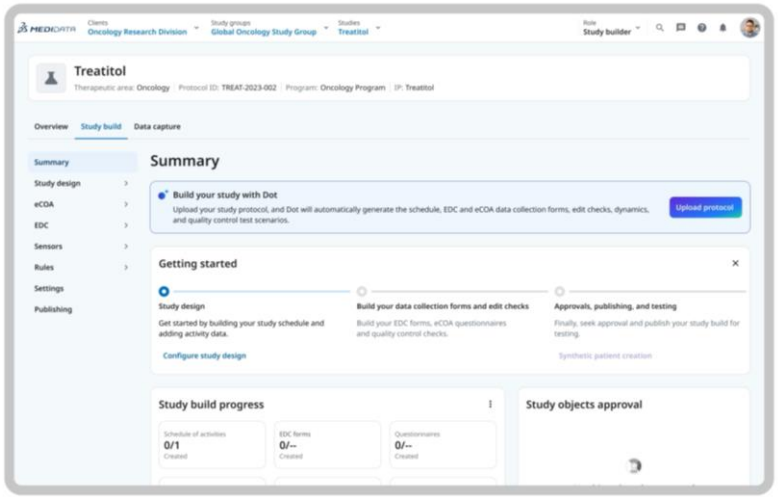


Rave Lite expands our reach in EDC to early and late phase studies while new AI capabilities and EHR connectivity solidify our base accelerating study build and site data collection. This together with new data acquisition experiences allows Medidata to capture a larger share of the overall trial data.

BIOPHARMA | CLINICAL ACCELERATION

Study Startup

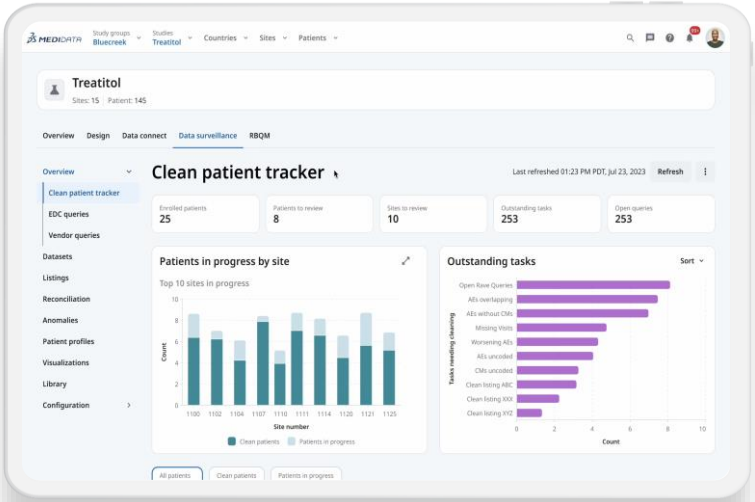


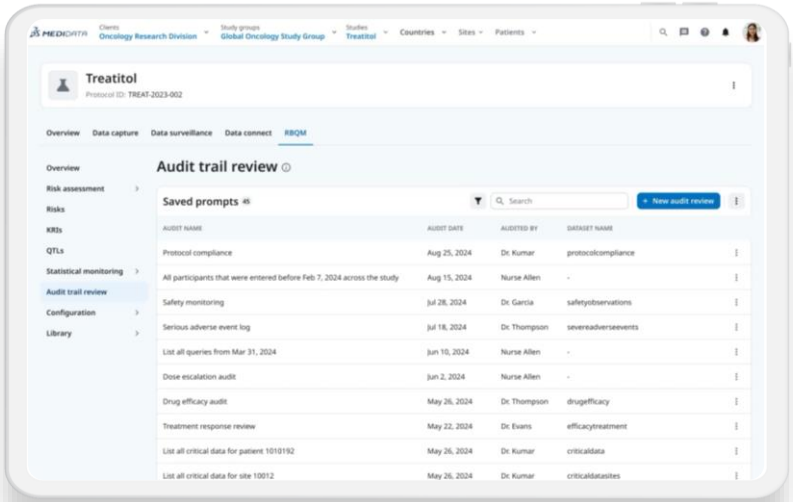


Leveraging AI to design, simulate, and execute faster more efficient clinical trials benchmarked with historical trials and automating study build steps accelerating time to site to first-patient-in.

BIOPHARMA | CLINICAL ACCELERATION

Clinical Data Science





Faster signal detection leveraging AI to automatically identify anomalies and manage and increasing complex ecosystem of data.

CLINICAL RESEARCH

Challenges

Manual data reconciliation; reliance on siloed data stores; difficulty accessing operational data to optimize planning.

Solution

A single data management experience using MEDIDATA Clinical Data Studio

Value

Break down data silos and seamlessly integrate into our current software stack

Process diverse clinical and patient data types provides increased efficiencies without sacrificing quality or needing additional resources

PHARMACEUTICAL DEVELOPMENT

Challenges

Manual data handling; data not available for planning/ decisions; information buried in scattered documents; knowledge kept at individual level; excessive late-stage lab work.

Solution

A single CMC lab informatics solution using BIOVIA ONE Lab

Value

Accelerated development and tech transfer with S88-complaint procedures

Automated lab processes with streamlined data acquisition

Eliminated redundant work with better knowledge-sharing

BIOPHARMA | FUTURE OF MANUFACTURING

Virtual Twin Experiences of Process and Plant

Accelerate new facility & product launches

Produce **several drugs simultaneously**, versus only one in current industrial sites.

Achieve more agile and flexible manufacturing

Take **days instead of weeks** to switch from manufacturing one drug to another (change-over)

Achieve Net-Zero Carbon objectives

Being carbon neutral

SAME-DAY BATCH RELEASE

Challenges

Increasing right-first-time efforts, removing paper for efficiency and sustainability, eliminating data transcriptions

Solution

A unified workflow across all QC laboratories using BIOVIA ONE Lab

Value

98% of analytical results acquired and issued automatically

Review times decreased up to 75%

Execution times decreased up to 50%

One single workflow on all QC laboratories

BIOPHARMA | END-TO-END PLATFORM

Improve Patient Outcomes by Elevating Indication and Therapeutics Knowledge and Know-How

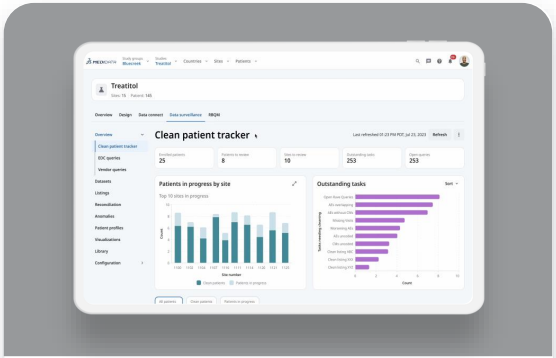
Develop

- Research & Discovery
- Preclinical
- Clinical Development & Supply
  - Phase 1
  - Phase 2
  - Phase 3

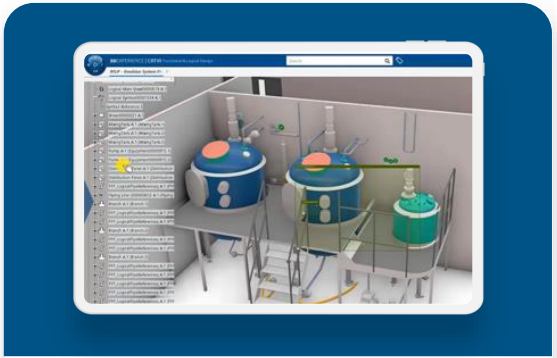
Supply, Manufacture & Control

- Commercial Manufacturing

Faster to IND
Speed to Patient



Clinical Development
Patient Outcomes



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Right First Time & Efficient Release

DASSAULT SYSTEMES