Digital Twins in Pharmaceutical Manufacturing

Christos Michos
Head, Digital Manufacturing Sciences
Global Manufacturing Sciences (GMSci)

March 2026

Better Health, Brighter Future

A global biopharmaceutical company

GLOBAL HEADQUARTERS
TOKYO, JAPAN

GLOBAL HUB
CAMBRIDGE, MA, USA

~25 NEW MOLECULAR ENTITY CLINICAL STAGE ASSETS

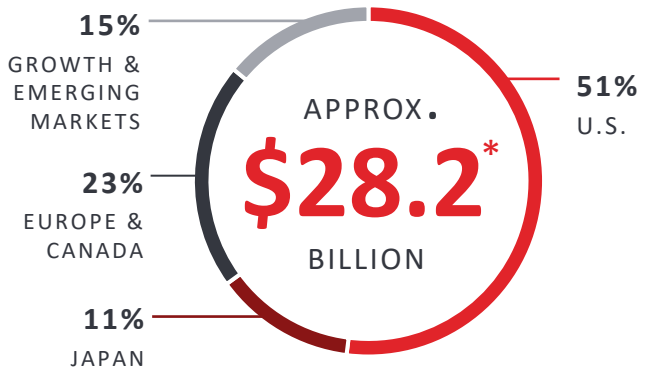
PRESENCE: APPROX. IN
80 COUNTRIES & REGIONS

25+ MANUFACTURING SITES

2 RESEARCH SITES

180+
PARTNERSHIPS TO HELP US BRING INNOVATION TO PATIENTS

FY23 REVENUE



* Convenience translation of reported JPY figures into USD at an average rate of 151.22 JPY/USD. FY2023 revenue amount as of March 31, 2024.

FOUNDED IN
1781
OSAKA, JAPAN

OUR PEOPLE

TOP EMPLOYER® IN
24
COUNTRIES & 3 REGIONS

NUMBERS AS OF JUNE 2024
UNLESS OTHERWISE INDICATED

The history of Takeda

Chobei I Takeda (1750-1821)

1781

Founded the company

- Started as a broker of Japanese/Chinese medicines in Doshomachi, Osaka
- Divided medicines from wholesalers into smaller batches for resale
- Keys to success: Fairness and Honesty
  - Reputed for exact weight and high quality
  - High confidence in medicines with the Chobei seal led to good sales

The "NORI" Code

1940

Formulation of "*Nori*"

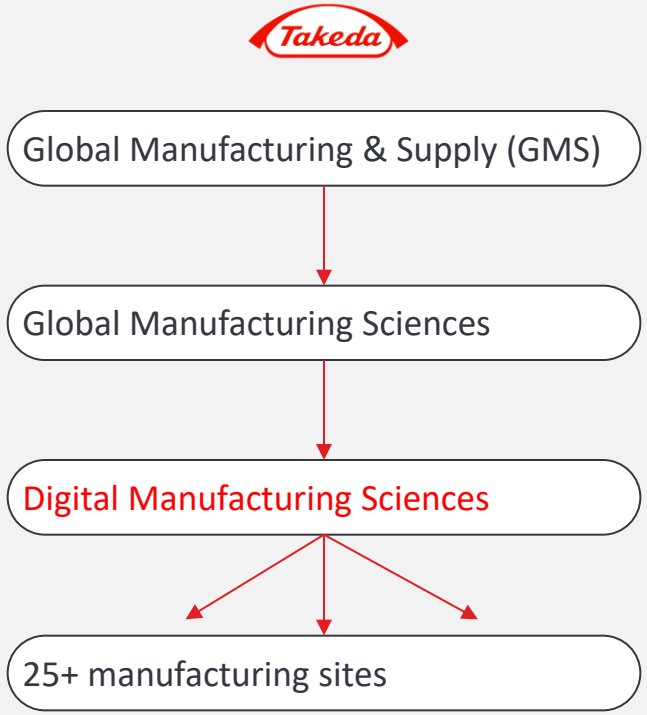
1. "Serve the public" — Integrity
2. "Work together in harmony" — Fairness
3. "Make efforts to study deeply" — Perseverance
4. "Esteem plainness" — Integrity
5. "Observe propriety" — Fairness, Honesty

The core of our culture: Takeda-ism

Our values of Takeda-ism incorporate Integrity, Fairness, Honesty, and Perseverance, with Integrity at the core.

Expansion into overseas market & globalization

Introduction



Christos Michos
Global Head,
Digital Manufacturing Sciences

Quick Bio:

- MSci, Mechanical Engineering, ETH
- ~10yrs at Takeda Pharma
- 1st Data Scientist in GMS back in 2017

- Swiss & Greek

- Father and Husband, 1yo Miltos, Maria

- Core Expertise: Digital Transformation

Global Dynamics Continue to Push the Pharma Industry to Accelerate Digital in Manufacturing, Supply and Quality

Business Dimension

Balancing short-term with long-term value

Big Pharma & Big Tech principles coming together (Operating Model)

DeepSeek moment for Pharma?

Technology Dimension

Invest in New systems vs keep legacy systems

IT/OT and the Cloud (the meaning of real-time)

Access to AI has to drastically increase

People Dimension

Technology Savvy Unicorns

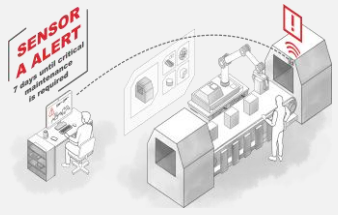
Resourceful workforce

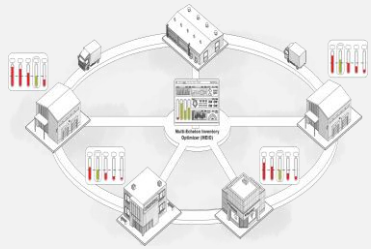
Human-AI interaction

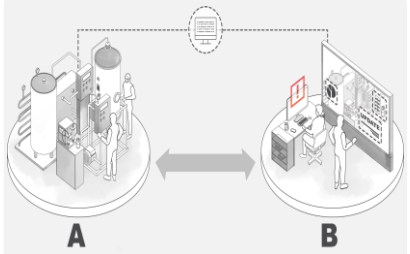
This changing reality demands Focus, Speed and Scale

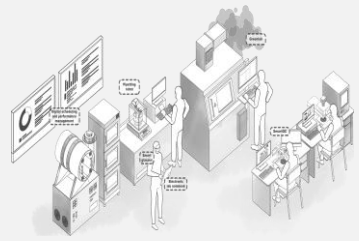
Focus, Speed and Scale with 6 Big Rocks

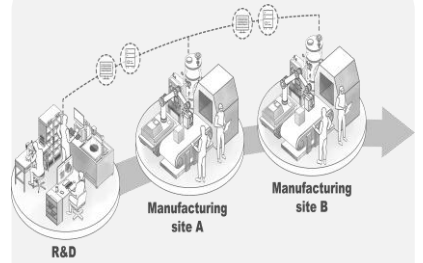
1	2	3	4	5	6
One Day Batch Release	Predictive Maintenance	Inventory Optimization	**Power of Digital Twins**	Lab of the Future	Rapid Digital Tech Transfer



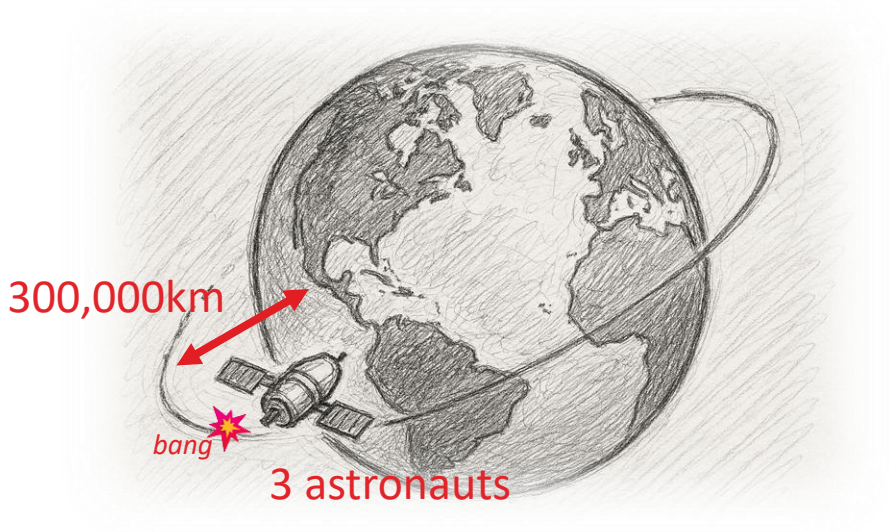








1970 – Apollo 13, the Birth of the First Digital Twin



How do you diagnose, and solve, the problem of a failing physical asset that is this far away and outside of direct human intervention?

→ **Simulate, when failure is not an option**

SOURCE: The first digital twin - Simcenter

Tech Transfers / Launches

>70 TT through 2030

Uninterrupted supply

process control

Troubleshooting

COGS reductions

process efficiencies / **yields**

Discard reduction

Simulate, which domain?

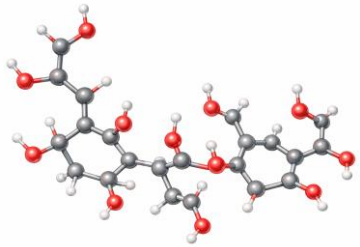
Metaverse of Digital Twins

R&D Research

Product Digital Twin

Targeting | Screening

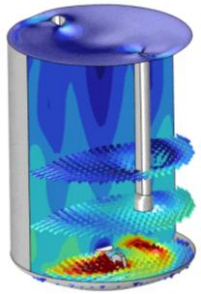
Formulation | Testing , Clinical



Manufacturing Sciences

Process Digital Twin

Control Strategy | Recipe
Scale-up | Tech Transfers | Launch



Engineering

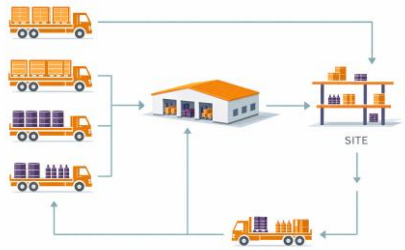
Plant Digital Twin

Building | Equipment | Environment
Resources | Maintenance

Supply Chain

Network Digital Twin

Distribution & Logistics | Demand & Supply |
MEIO, Inventory

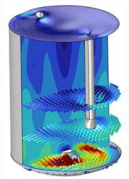


Simulate, what?

Manufacturing Sciences

Process Digital Twin

Control Strategy | Recipe
Scale-up | Tech Transfers | Launch



Simulation Universe for Manufacturing Sciences (MSci)

Approval / Launch

Phase 3 or Process Transfer	Filing	Manufacturing
Science / Engineering		
DoE Model-based DoE		**Cont. Improvement** Model-based process improvements
Scale-up Model-based Scale Up	**Eng. Run** Virtual Engineering Run	**PPQ** Model-based de-risking	**Monitoring & Control** CPV, Golden Batch, AI/ML Anomaly Detection
Plant | Line | Equipment **Model-based Facility Fit** Virtual plant, line, equipment design	**Commissioning & Qualification** **Virtual Commissioning** Testing Fluid Flows and Automation Logic		**Predictive Maintenance** Model-based maintenance

Opportunities for CMC Changes

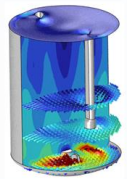
Costs, Complexity & Effort of CMC-Management

Simulate, what exactly?

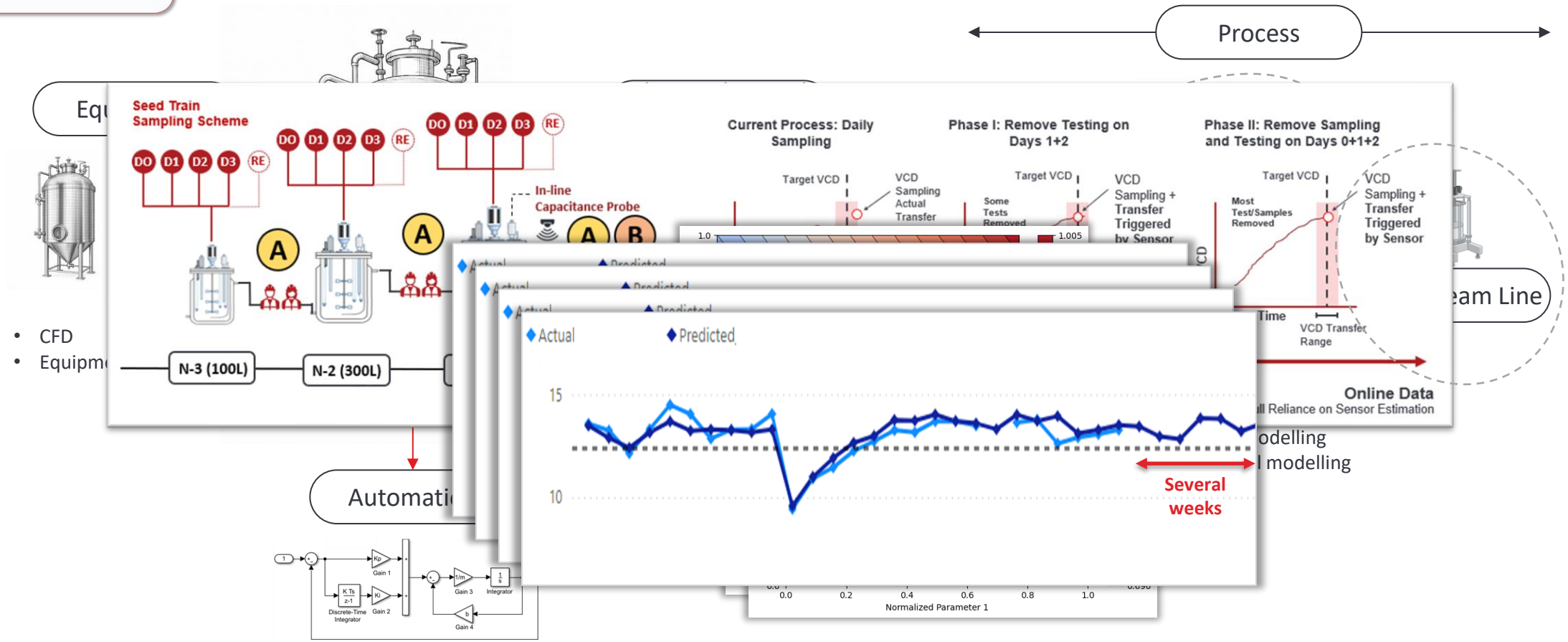
Manufacturing Sciences

Process Digital Twin

Control Strategy | Recipe
Scale-up | Tech Transfers | Launch



Deep Dive into Manufacturing Sciences' Continuous Improvements



Simulate, where?

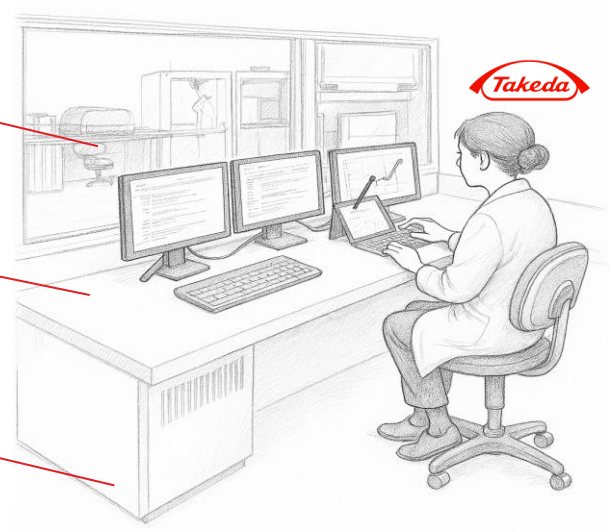
Type of Digital Twin?

Type I — Before or After Processing

Troubleshooting

Process Improvements

Tech transfers



Where
In a Control Room

Who
MSci,
Quality,
Eng

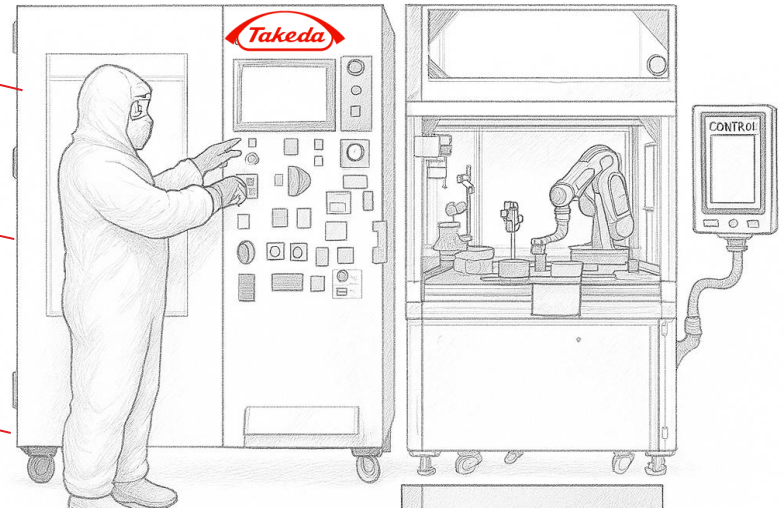
What
LCM
TT

Type II — During Processing

Adaptive Process

Real-Time intervention

Advanced Process Control



Where
Shop-floor

Who
MFG

What
Commerical portfolio

IT/OT complexity, regulatory complexity, maintenance, PAT

Simulate, how?
Our Journey towards improved decision making with Digital Twins

-2020

1 *Following the AI craze*

Using classical machine learning to make informed business decisions

Black Box
Probabilistic

Challenges

High data demand
Lack of explainability
Lack of trust in BB

Typical Use Case

Yield prediction
enabling proactive
process monitoring

2020+

2 *Bringing AI Closer to Pharma*

Using experimental verification augmenting classical machine learning

Black Box
& Lab

Challenges

High data demand
Time and cost (due to experiments)

Typical Use Case

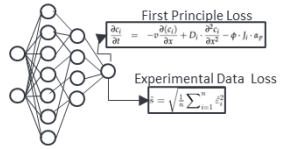
Yield improvements / Increased Batch Size
Process Improvements
Investigations / Troubleshooting

2023+

3 *Fusing together Big Tech with Big Pharma*

Using first principle equations from chemistry / physics and artificial intelligence

Black Box
& White Box



Challenges

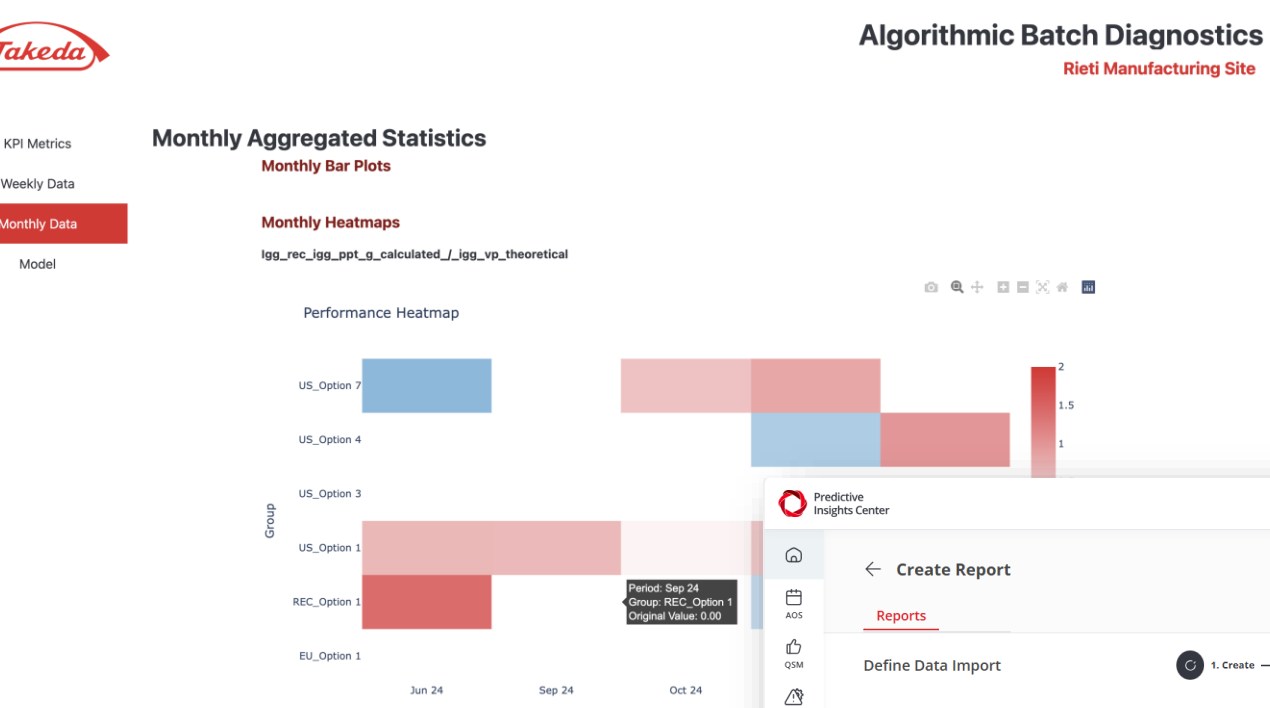
High data demand
High expertise required

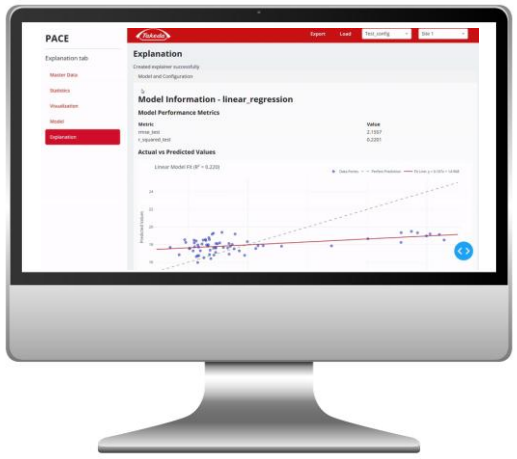
Typical Use Case

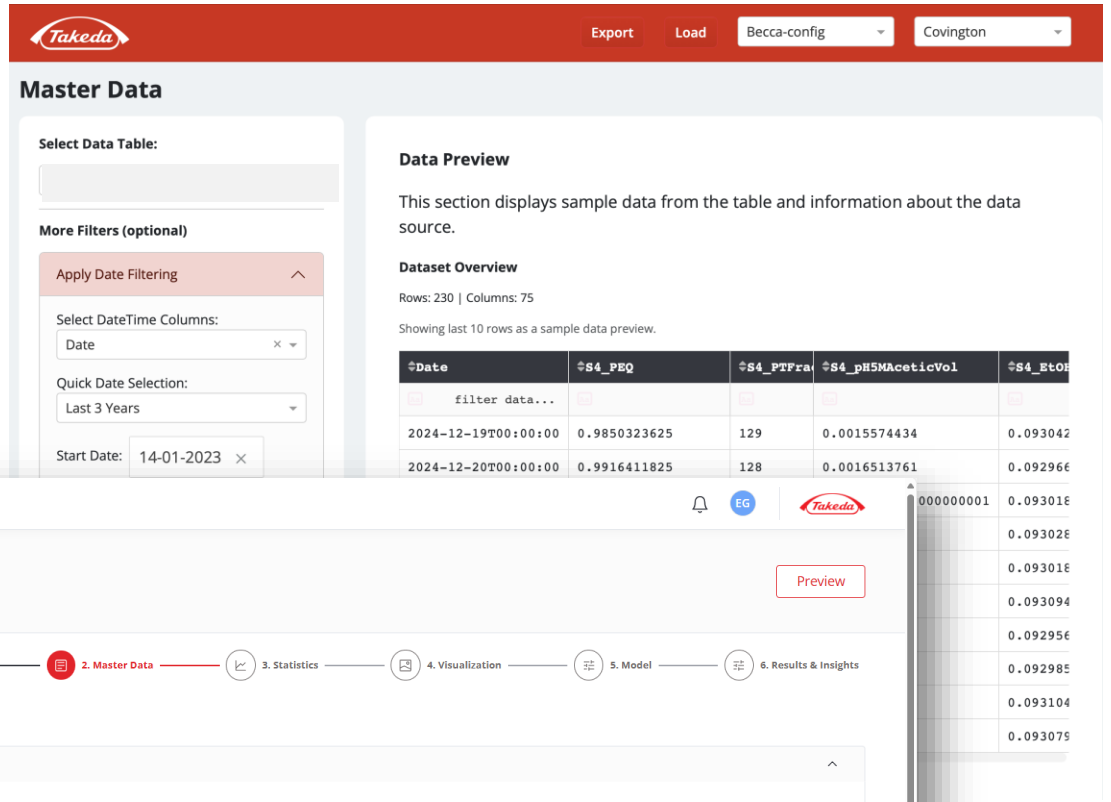
Yield improvements / Increased Batch Size
Investigations / Troubleshooting
Predictive Monitoring

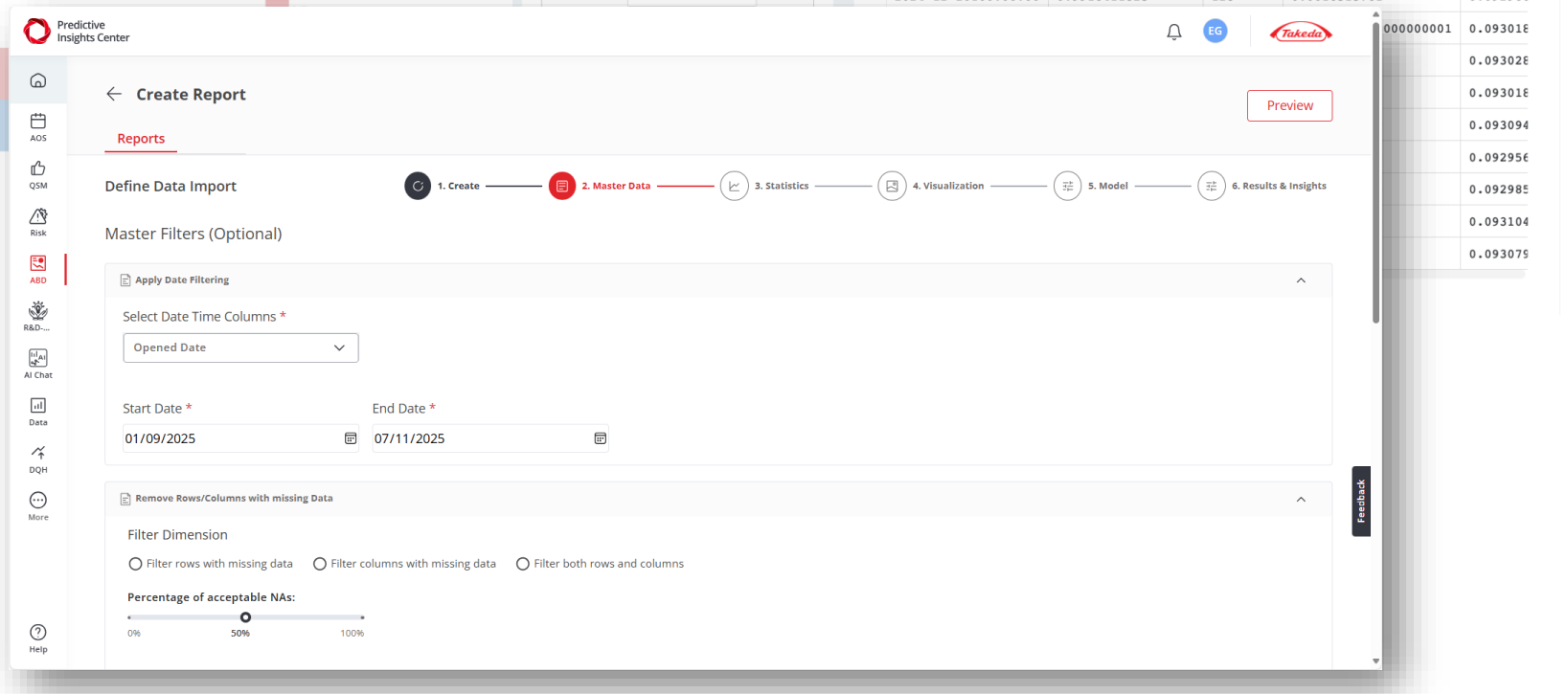
Systemic impact

Algorithmic Batch Diagnostics: Connecting Data, Modeling and Customized SME Reports in one Pipeline





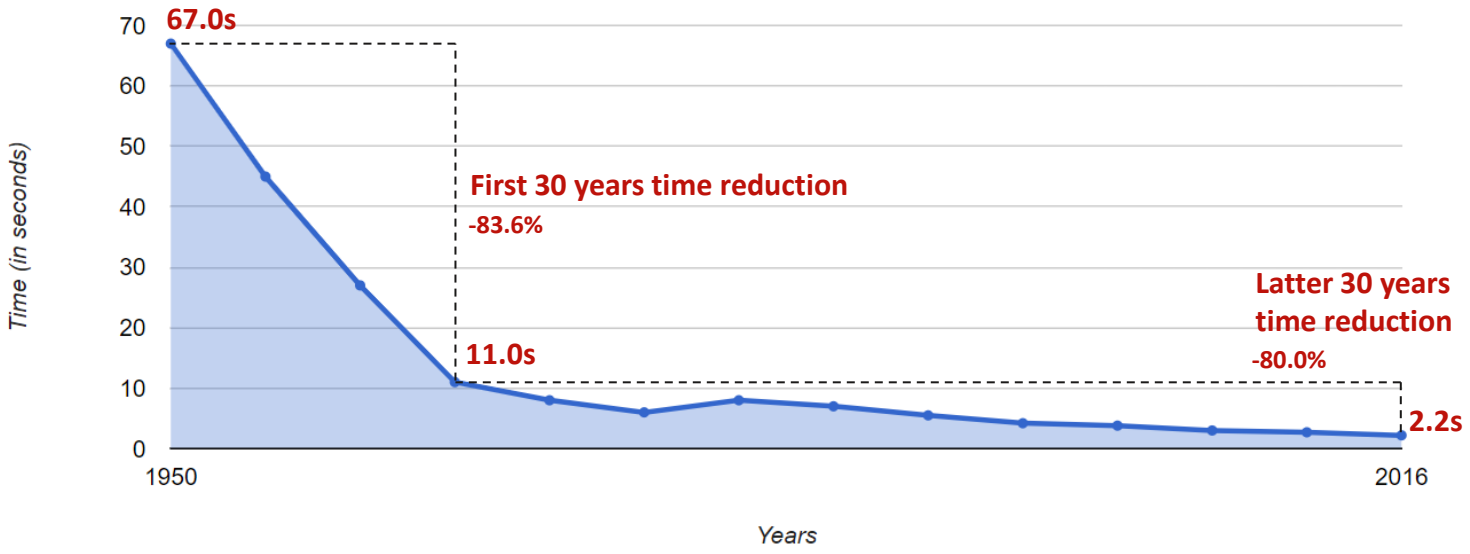




Digital Transformation: Insights From Formula 1

Formula 1

Average Pit Stop Time Through Years



Analogy: Formula 1 pitstop time reduction reflects the transformative impact of **technological advancements and process optimization.**

Biopharma: Transition from manual, reactive modeling to integrated digital twins significantly boosts operational efficiency and business value.

Reasons for Pit Stop Time Reduction:

Technological Advancements
- High-speed pneumatic tools
- Improved tire technology

PAT, Soft Sensors, Cont. Processing

Process Optimization
- Standardized procedures
- Intensive training and regular drills

Digital Workforce, Workflows and Workspace

Team Specialization
- Clear role delineation
- Enhanced team coordination

Cross-functional. AGILE delivery teams with OKRs

Car Design Enhancements
- Accessible wheel nuts
- Optimized car structures

Single-use equipment, Perfusion Reactors

Data Analytics
- Performance monitoring
- Real-time adjustments

Digital Shadows, Twins, Cloud Systems

Regulatory Adaptation
- Adjusting strategies and techniques to new regulations

Proactive EMA/FDA Guideline Adoption

FOCUS OF DIGITAL TWIN PROGRAM

SOURCE: https://statathlon.com/analysis-of-the-pit-stop-strategy-in-f1/

APPENDIX

The Pharma Industry Is In the Early Stages of Being Disrupted

The Drug Industry Is Having Its Own DeepSeek Moment

It isn't just artificial intelligence—Chinese biotechs are now developing drugs faster and cheaper than their U.S. counterparts

By David Wainer Follow

Feb. 7, 2025 5:30 am ET

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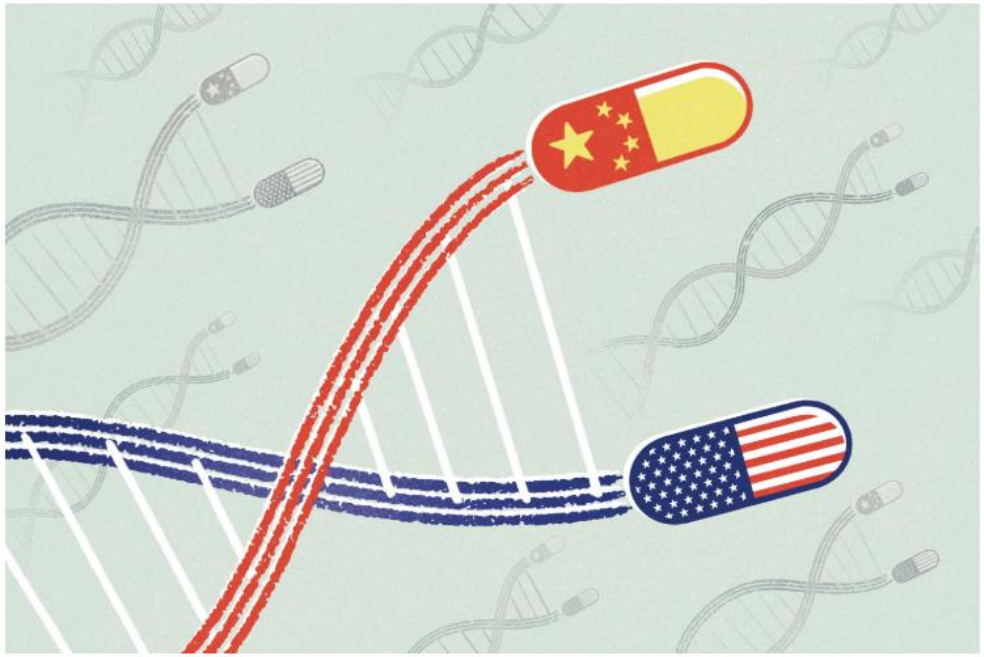

THE WALL STREET JOURNAL.

- **China's biotech boom mirrors its rise in tech**
- Chinese innovation is steadily improving and **is already starting to disrupt the U.S. drug-development** ecosystem

SOURCE: Chinese Biotech Is Having A DeepSeek Moment - What's News - WSJ Podcasts

Big Tech Perspective

Nvidia CEO Jensen Huang: Drug research will be transformed

Nathan Bomey

Add Axios on Google

Nvidia CEO Jensen Huang speaks during the World Economic Forum (WEF) annual meeting in Davos on Wednesday. Photo: Fabrice COFFRINI / AFP via Getty Images

Nvidia CEO Jensen Huang predicted Wednesday that drug research will shift from traditional labs to AI platforms, with pharma giants already making the leap.

SOURCE: Nvidia CEO Jensen Huang at Davos: Drug research will be disrupted

Bill Gates: Within 10 years, AI will replace many doctors and teachers—humans won't be needed 'for most things'

Published Wed, Mar 26 2025•9:05 AM EDT

Tom Huddleston Jr.

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Trending Nov

1 I send this 10-wo regularly to frien colleagues and r remembered is s powerful'

SOURCE: Bill Gates on AI: Humans won't be needed 'for most things'

Reuters

World Business Markets Sustainability Legal Commentary Technology Investigations

Takeda deepens AI drug discovery push with $1.7 billion Iambic deal

By **Kamal Choudhury**

February 9, 2026 2:04 PM GMT+1 · Updated February 9, 2026

SOURCE: Takeda deepens AI drug discovery push with $1.7 billion Iambic deal | Reuters