



Managing Quality in Pharma Manufacturing

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Transforming a world of data into a world of intelligence

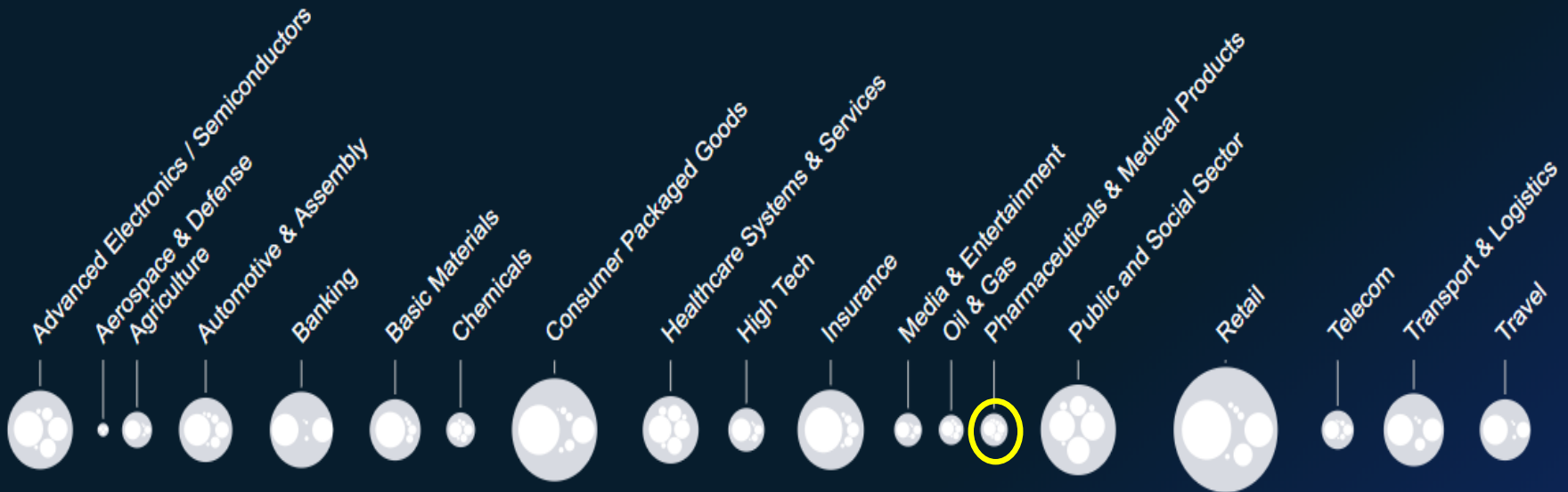


Usage and Impact of AI and other Analytics

Potential total annual value of AI and analytics across industries

\$9.5T - \$15.4T

- Tap an industry to size the opportunity -



Usage and Impact of AI and other Analytics

All Industries

Pharmaceuticals & Medical Products

Total potential annual value up to

\$441.3B | **22.02%** of sales

Traditional AI and analytics

\$318.9B

\$122.4B

Advanced AI

% of value driven by advanced AI

- Tap a function to value AI/analytics domains -

100%

50%

0%

Marketing
& Sales

\$218.7B

\$171.9B \$46.8B



Supply Chain
Management
& Manufacturing

\$88.9B

\$53.3B \$35.7B

Product
Development

\$74.6B

\$42.7B \$31.9B

Strategy
& Corporate
Finance

\$23.7B

\$23.7B

Service
Operations

\$13.1B

\$13.1B \$0.0

Risk

\$7.5B

\$6.0B \$1.5B

Other
Operations

\$5.8B

\$4.0B

Finance
& IT

\$4.8B

\$1.7B

HR

\$4.2B

\$2.5B \$1.7B



Usage and Impact of AI and other Analytics

All Industries

Pharmaceuticals & Medical Products

Supply Chain Management & Manufacturing

Total potential annual value up to

\$88.9B | **4.44%** of sales

Traditional AI and analytics

\$53.3B

\$35.7B

Advanced AI

% of value driven by advanced AI

- Tap a domain to see business use cases and their requirements -

Sales
& Demand
Forecasting

\$36.4B

\$29.2B \$7.3B

Predictive
Maintenance

\$31.9B

\$12.7B \$19.1B

Yield,
Energy,
& Throughput

\$13.6B

\$8.1B \$5.4B

Inventory
& Parts
Optimization

\$5.1B

\$3.0B \$2.0B

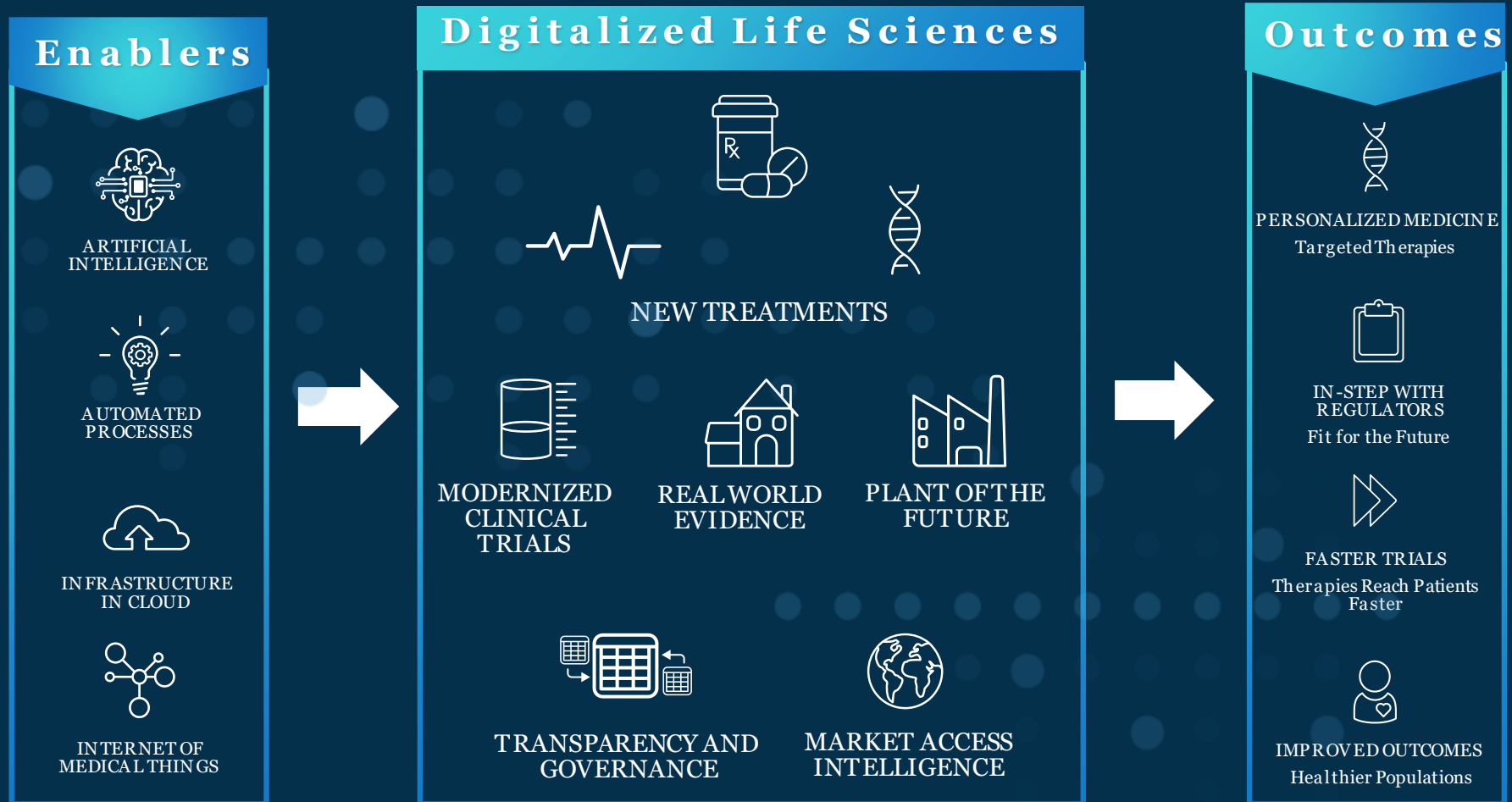
Procurement
& Spend
Analytics

\$2.0B

\$200.4M \$1.8B

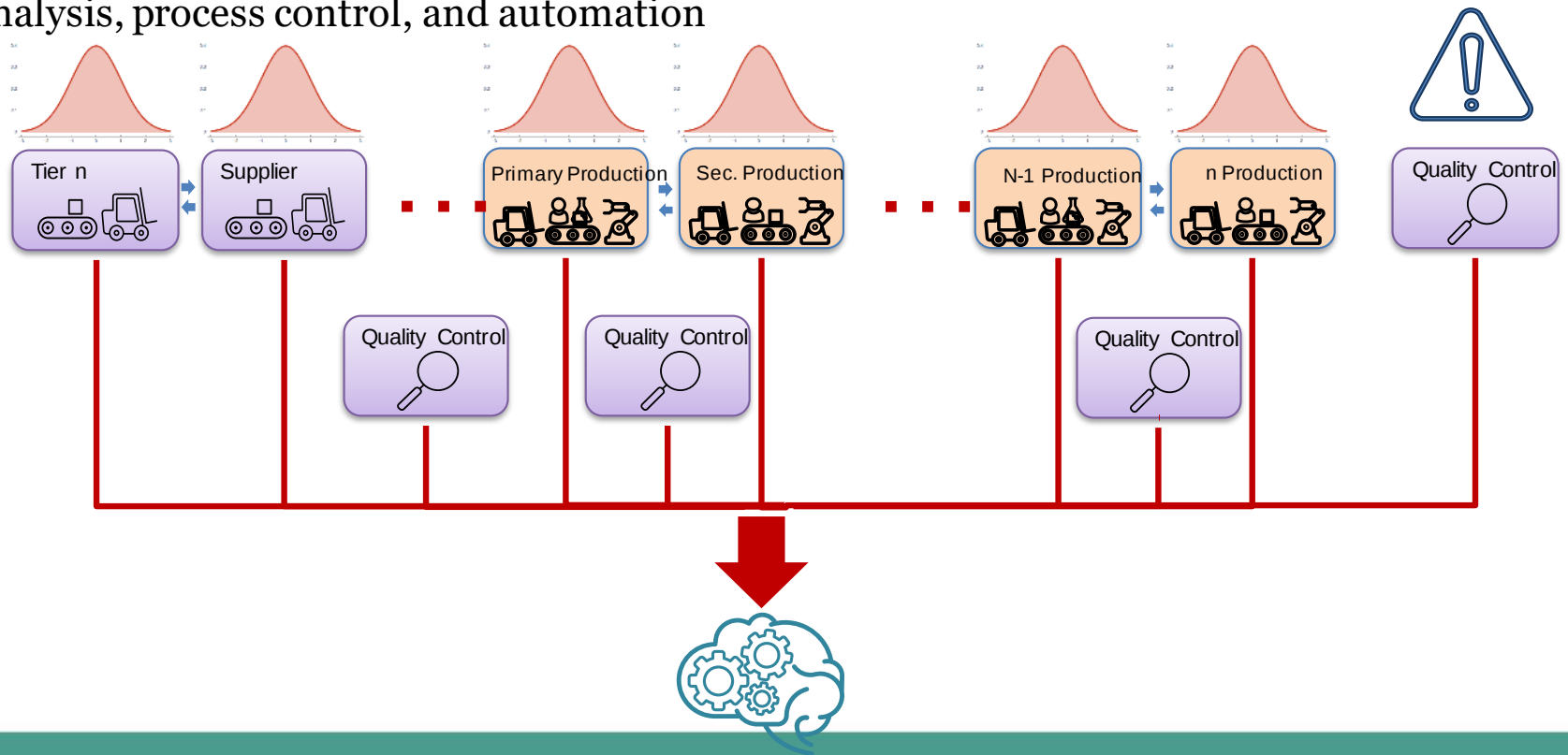


Analytics Drives the Age of Digital Health



What are Clients talking about Quality Globally ?

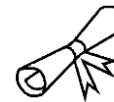
- **Quality assurance** is ensured by end-product testing, i.e., quality by testing and inspection and not always by design or by any proactive measure
- Significant **opportunities** exist for improving pharmaceutical development, manufacturing, and quality assurance through **innovation** in product and process development, process analysis, process control, and automation



92%
OEE

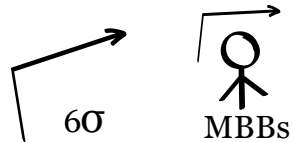
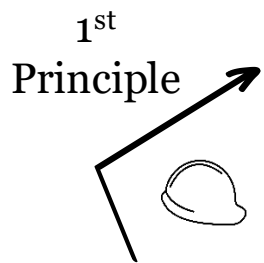


Profit / Revenue

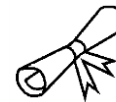


Industry 4.0 (**14.75% CAGR 2022**)

92%
OEE



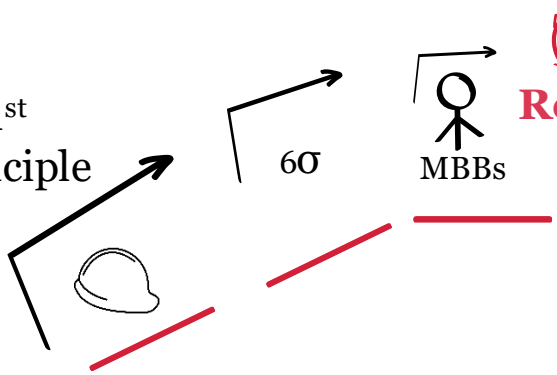
Profit / Revenue



Industry 4.0 (**14.75% CAGR 2022**)

92%
OEE

1st
Principle



The diagram illustrates a progression from a hard hat icon to a stick figure icon labeled 'MBBs'. A black arrow points from the hard hat to the stick figure, with the text '1st Principle' above it. A red arrow points from the hard hat to the stick figure, with the text '6σ' above it. A red line connects the hard hat to the stick figure.

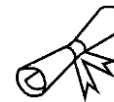
6σ

MBBs

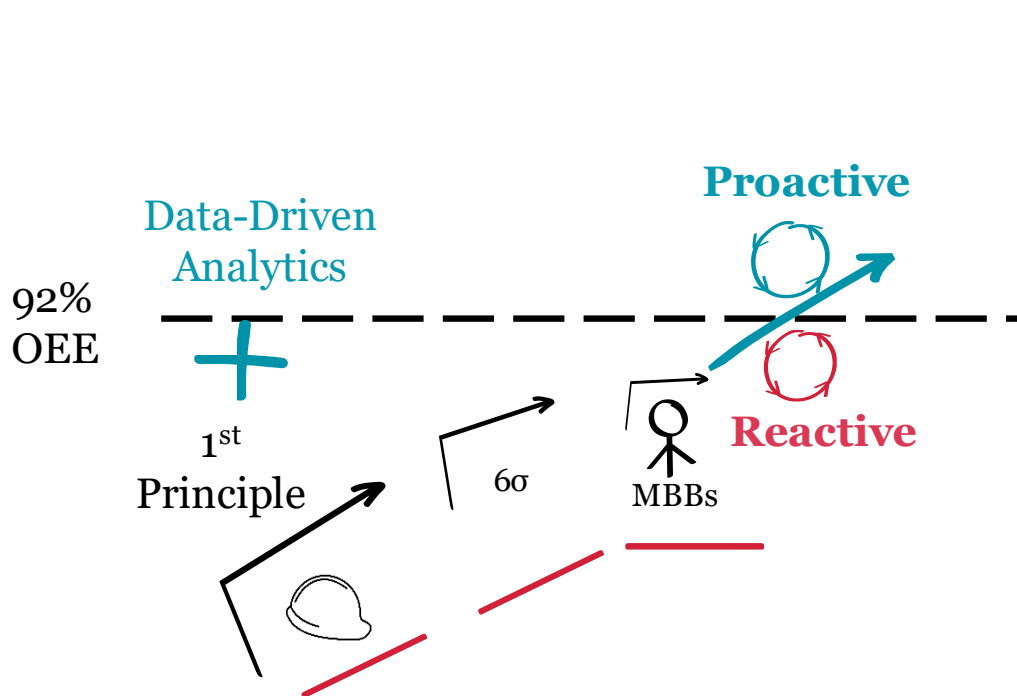
Reactive

Culture

↓ Profit / Revenue

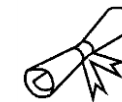


Industry 4.0 (14.75% CAGR 2022)



Culture

Profit / Revenue



Industry 4.0 (**14.75% CAGR 2022**)

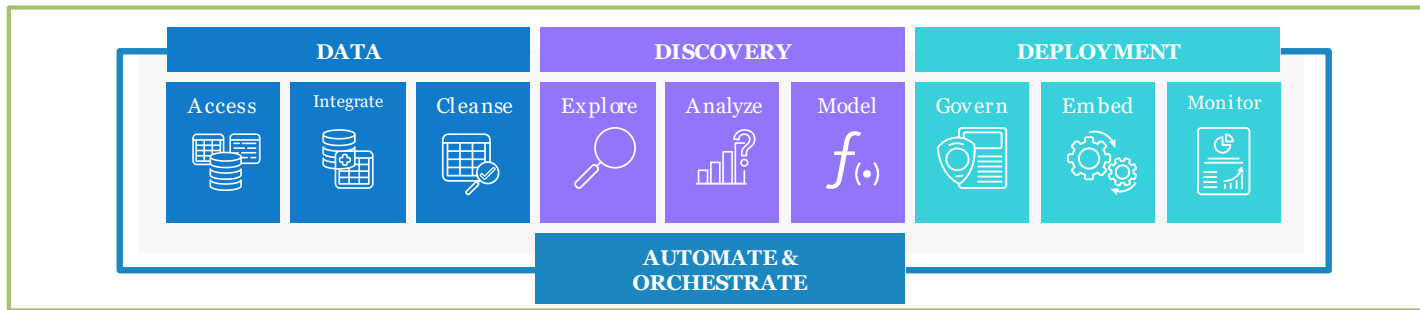
- + in-situ machine data
- + environmental sensor data
- + IT and OT data

Align Analytical Capabilities to the Quality Maturity

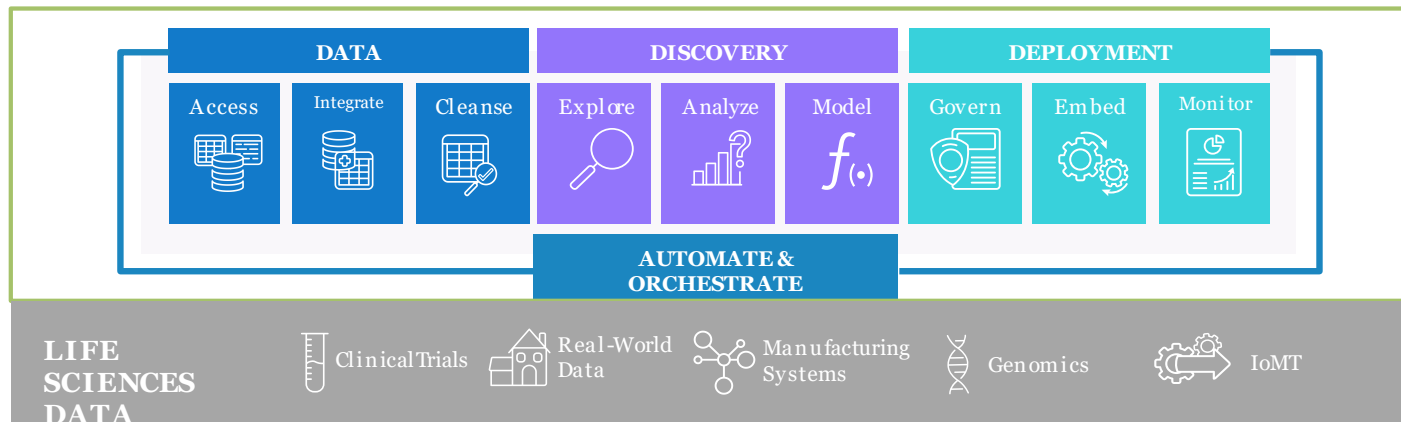


QM Strategy					Focus	Question
Process Optimization / Digital Twin	Integrate quality, AM, engineering and operations data	Combine decision functions in one operations center	Optimize quality, maintenance, ops & engineering		Optimization/ Digital Twin	What's the best that can happen?
Quality Prediction & Advanced Process Control	Monitor production quality in real-time	Optimize process settings and predict yield	Predict EOL quality issues at an early process stage		Predictive Modeling	What will happen next?
Process Quality Assurance	Ensure process quality	Adjust process settings to assure quality	Implement proactive quality management	Increase throughput and yield	Forecasting/ Simulation	What if these trends continue?
Root Cause Analysis	Understand causal factors	Determine variables that impact quality	Apply statistics to explain adverse effects	Build data based process understanding	Statistical Analysis	Why is this happening?
Statistical Process Control	Apply thresholds and automatically trigger alerts	Notify stakeholders	Alert and incident management		Alerts	What actions are required?
Real-time Quality Reporting	Use integrated quality data as "one version of the truth"	Automated real-time reporting on OEE, yield throughput, etc.	Detect quality issues at an early stage		Query/Drilldown	Where exactly is the problem?
Self Service Quality Reporting	Use integrated quality data as "one version of the truth"	Selfservice reporting on OEE, yield, throughput, etc.	Get an overview of production quality		Ad hoc Reports	How many, how often, where?
Production Quality Reporting	Unstable process and production quality	Scattered data sources	Manual standard and ad hoc reporting on production quality		Standard Reports	What happened?

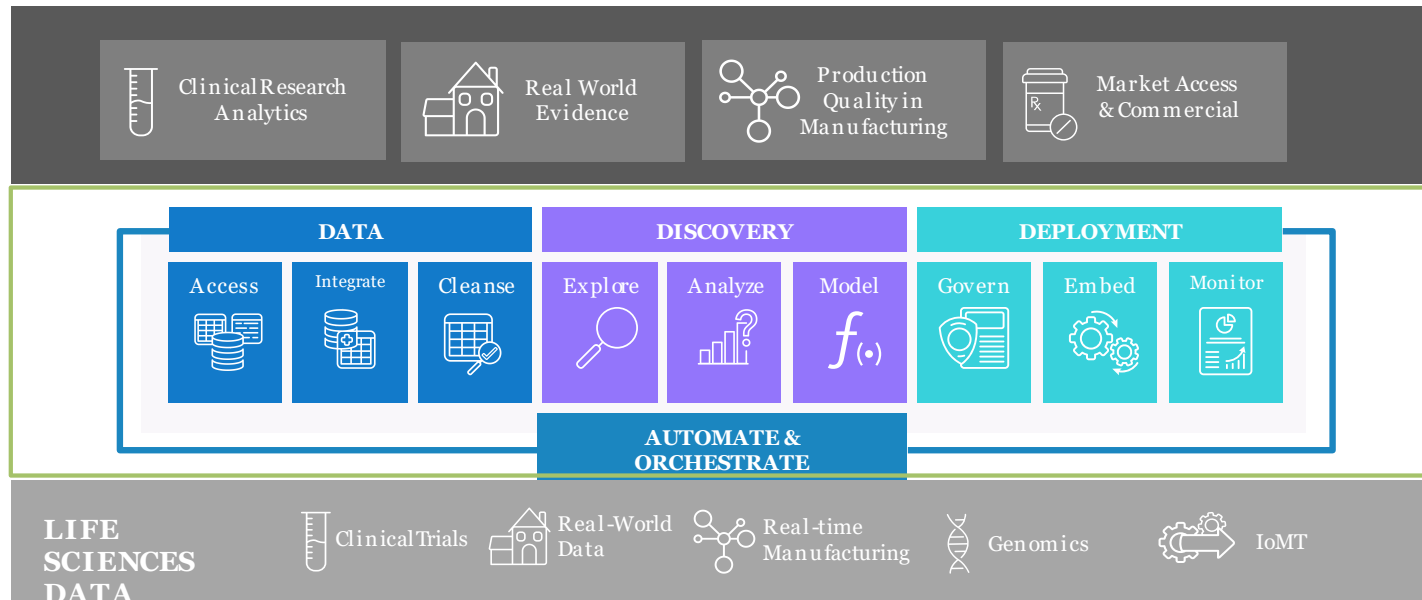
Accelerating Tangible Value from Analytics



Accelerating Tangible Value from Analytics



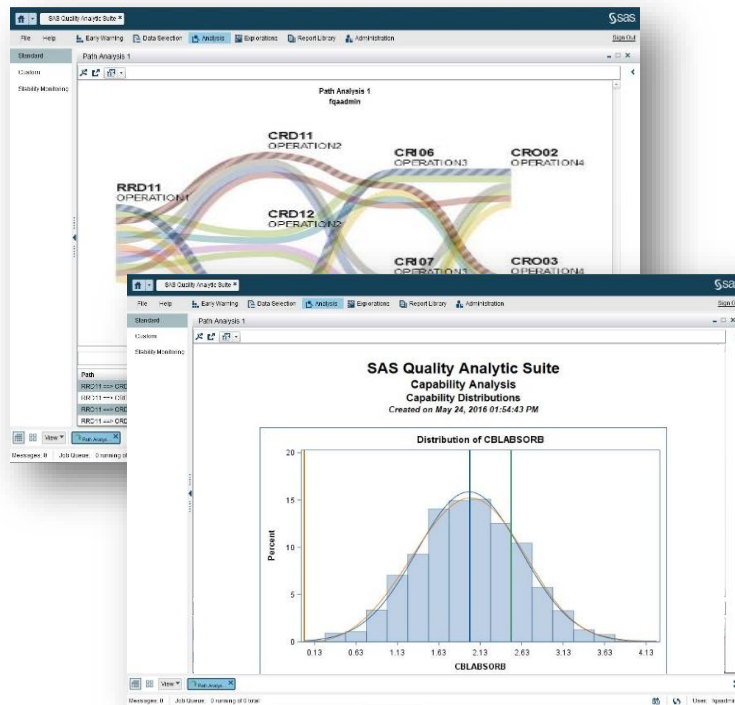
Accelerating Tangible Value from Analytics



How SAS delivers value to customers

Production Quality Analytics

SAS® Production Quality Analytics allows organizations to implement a closed-loop process to identify quality problems within the manufacturing process and take immediate remedial action.



Shortened time to market

Establish control and reduce variation

Determine process capability

Shorten cycle times

Improved Problem Resolution

Pinpoint critical problems quickly

Gain process understanding.

Performance Improvement

Reduce waste and rework

Improve products and processes

SAS is the only analytics vendor delivering an integrated analytical platform in a GMP-compliant environment for the pharma industry.



Few Selected Case Studies



SAS was implemented by a major global pharmaceutical company to support its initiative to

- 1. Improve manufacturing efficiency and move toward zero defects and zero waste**
- 2. Faster detection of quality issues to avoid rework**

Improving Manufacturing Production Quality

Manufacturing process is tightly controlled & formally regulated, 50% waste in pharmaceutical manufacturing is not uncommon & clearly quality control is paramount.

Business Challenge :

Client was in a situation of increasing costs and reducing profitability, they initiated a program to improve manufacturing efficiency and move toward zero defects and zero waste.

- First, they needed to understand root causes of manufacturing batch failures—but the process was complex, & hampered by poor performance of its existing analytics approach.
- They needed a global platform to empower its reviewers with access to near real-time data.

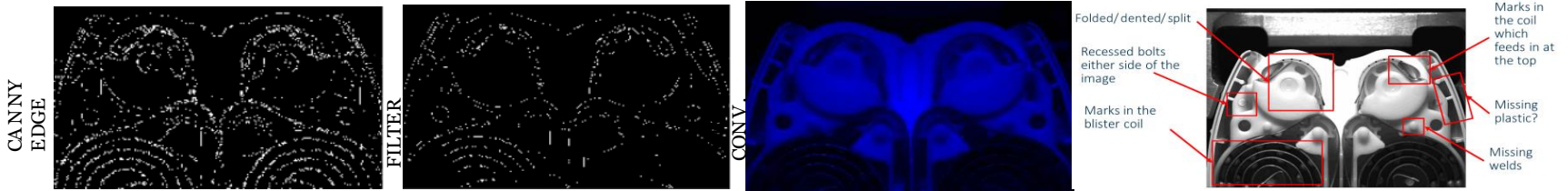
Results with SAS:

- We positioned ourselves as having not only the heritage and key competence around analytics, but also the vision to deliver rapid execution and results of visualization.
- Having both sides of the coin available from one vendor, and a specific SAS® Production Quality Analytics solution, we demonstrated SAS' ability to deliver what client needed: faster, at lower cost, and with greater ability to adapt to their future needs.
- That vision proved true with client going live in production after only six months of development testing

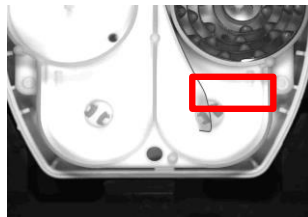


Asthma Inhaler Production

Using Computer Vision, ML and AI models SAS predicted good/bad inhaler images with 99% accuracy.



Using the PoC models SAS delivered prediction scores for 900K+ potentially faulty devices produced on line #6, allowing the quality teams to identify the defective devices and ship the remaining non-defective ones to patients.



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