Digital Transformation for Life Sciences

Accelerate discovery and operations using integrated digital systems

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We believe in the power
of digital transformation to drive
operational excellence.
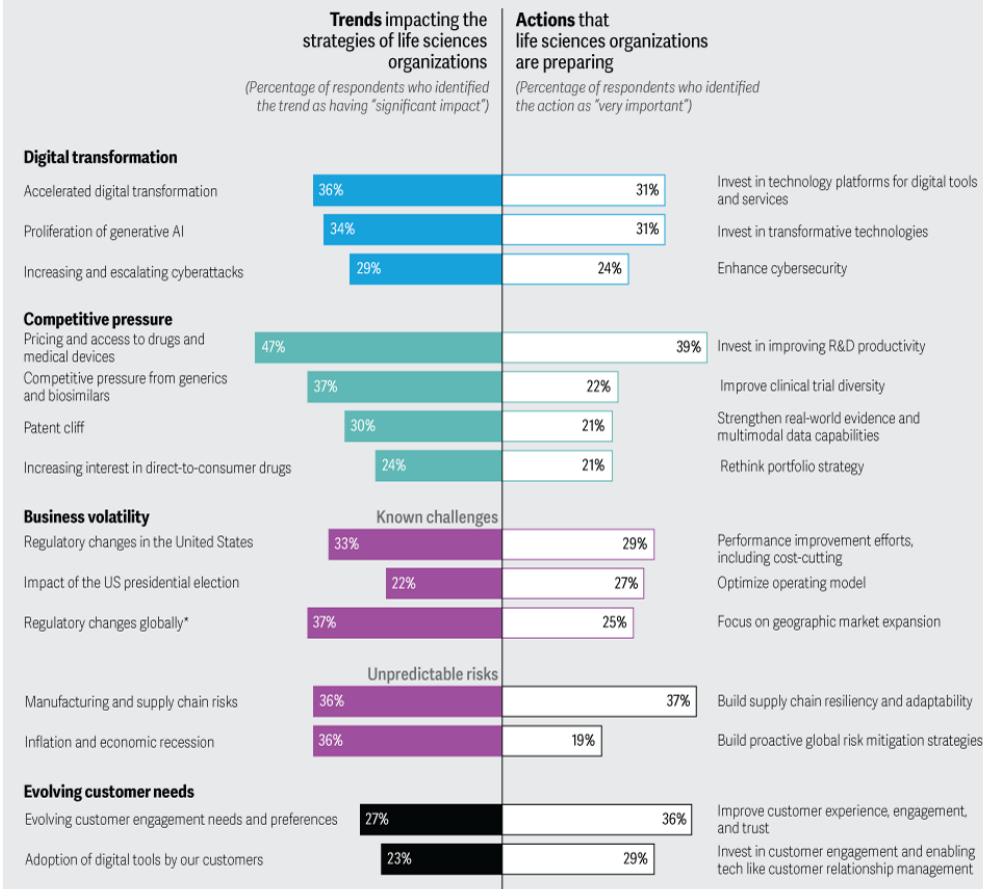
Digital Transformation for Life Sciences

Changing the way the game is played

DX a Strategic Priority for Life Sciences

- According to Deloitte, AI is being deployed to accelerate drug discovery, streamline operations, enhance the customer experience, and more

- Nearly 60% of companies surveyed are moving beyond pilot projects and are beginning to realize substantial value from adopting these technologies at scale

- Investments by biopharma companies over the next five years could generate up to 11% in value relative to revenue across functional areas

- To fully realize this potential, life sciences leaders should prioritize strategic issues that can most benefit from gen AI

Source: Deloitte 2025 Life Sciences Outlook survey

Harness Your Data. Unleash Your Operation.

AI provides life-sciences companies with unprecedented power to enhance their products, services, operations, and strategic decision-making.

Drug Discovery

- Drug discovery is accelerated by the ability to efficiently analyze large datasets to pinpoint potential drug candidates more accurately
- Clinical trials can be streamlined, resulting in quicker commercialization

Production

- Production processes are monitored and improved in real-time
- Issues are detected earlier, allowing time to resolve. The result is minimized defects and deviations
- Proactive maintenance using actual metrics vs duration-based activities increase efficiency and reduce downtime.

Regulatory

- Automate compliance monitoring and reporting
- Predictive models can identify and address risks related to product recalls and supply chain disruptions, protecting patient safety and brand reputation
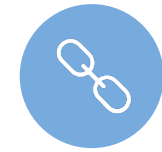
Supply Chain

- Predictive models facilitate real-time demand forecasting, improve inventory management, and enhance supply chain visibility, reducing stockouts and lowering holding costs while increasing resilience

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Incorporate AI/ML at Every Stage of Operations

Add AI/ML and increase your productivity exponentially in key areas of your lab and manufacturing operations.

Accelerating Bench Scale Process Development

Process Design & Simulation

Process Monitoring & Control
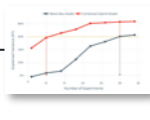
Real-Time Testing

Automating Pilot Scale Manufacturing

Process Optimization Simulation

Process Monitoring & Control

Real-Time Testing

Enabling Agile Scale-out at Commercial Scale Manufacturing

Process Orchestration
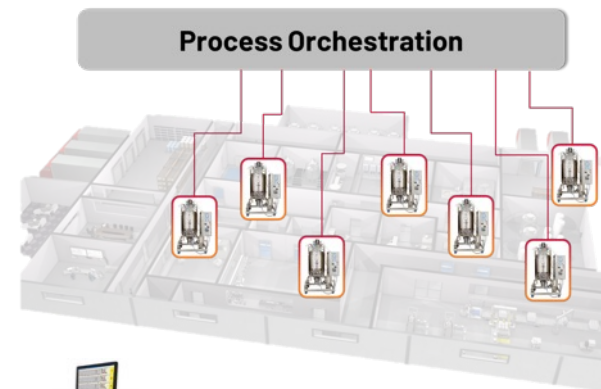
Agile Modular Plant Orchestration

Real-time testing & Supervised Closed-Loop Control

Digital Twin

Process Development → **Pilot Programs** → **Compliance** → **Commercial Manufacturing**

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How to Begin: Focus on a Use Case and Data

- Work with experts to gain a complete business understanding of the initial use case(s)
  - Value generated, GM Optimization, ROI metrics
- Complete an inventory of all the data required for the initial use case
  - Map the data hierarchy and structure
  - Focus on a reusable ecosystem that has high data reuse from use case to us case
- Train the model and evaluate the results
- Learn, improve, scale
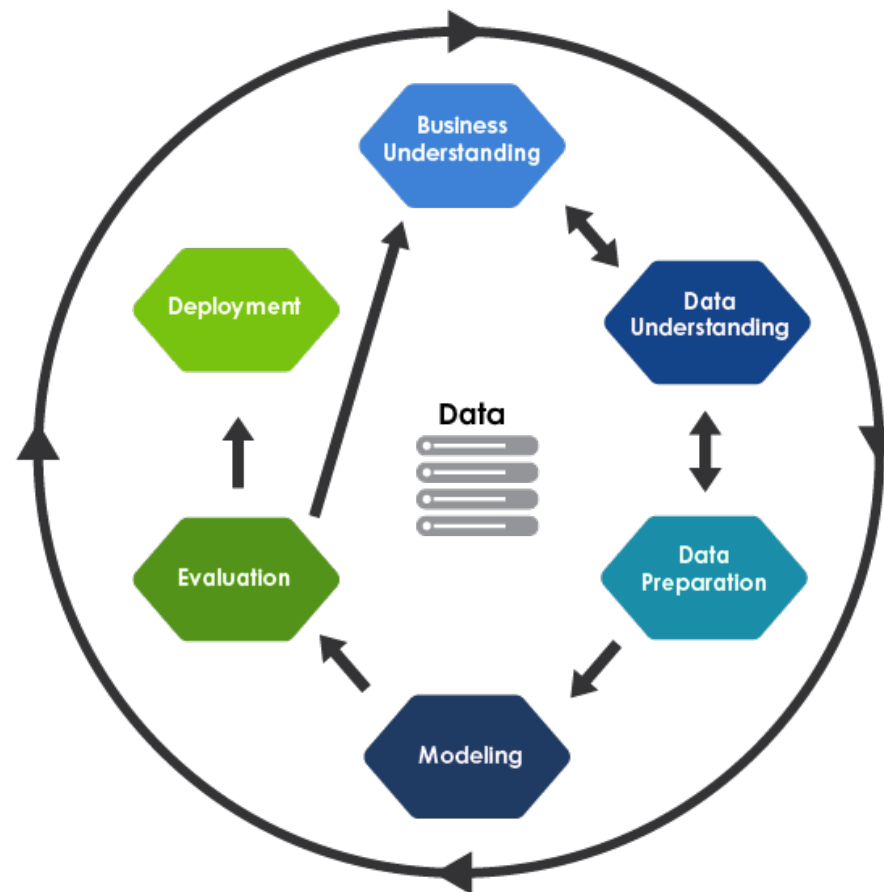
Published in 1999, Cross-Industry Standard Process for Data Mining (CRISP-DM) has become the most common methodology for industrial data mining, analytics, and data science projects.

Use Cases

Accelerating discovery, trials, and operations

Drive Operational Excellence Across Your Enterprise

Deliver highly flexible, scalable, reliable, maintainable and secure integrated digital environment to enable efficient highly automated manufacturing and order fulfillment processes.

Quality and Regulatory Control
- Product , Material and Equipment Traceability
- Process, Product and Equipment Data Historization
- Environmental & Safety Systems Monitoring
- System & Process Validation

Process Control Optimization
- Process Monitoring
- Process Analytics
- Statistical Process Control (SPC)
- Adaptive Process Control

Asset Reliability
- Asset Management & Monitoring
- Asset Condition & Health Analytics
- Asset Reliability Optimization
- Predictive Maintenance

Guided Operations
- Integration of all manufacturing data and activities
- Expert System Orchestration for best practices
- Visibility to exceptions and quality issues
- Qualified sub-processes

Energy Optimization
- Energy Metering & Monitoring
- Energy Efficiency
- Energy Consumption & Cost Analysis
- Energy Optimization

Agility & Flexibility
- Full Digital Integration
- Wireless Mobile Communications
- IIOT –Edge to Cloud, Smart Devices.
- Web Based Service Oriented Data Integration

Connected Worker
- Collaboration, Notification and Immediacy
- Mobility, scan, image capture
- Intelligent verification and e-signatures

Material & Batch Optimization
- Material & Batch Tracking & Genealogy
- Batch Process Monitoring
- Batch Performance Analysis

Operational Excellence
- Manufacturing Operations Management
- Quality, Production, Maintenance, Inventory, Safety
- Changeover Optimization, Custody Transfer

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Use Case: Cellular Cultivation in Oncology

Challenge

- Apply AI/ML to various aspects of CAR-T therapy to enhance the understanding, development, and optimization of these advanced therapeutic modalities

Solution

- Track process parameters, set points and sequential actions into a time-series historian with data sets identified by tag name and timestamp from 1-to-15-minutes

- Clustering model for categorization of data sets drives anomaly detection when future data sets behave differently than past data

Results

- A properly trained AI/ML engine can monitor conditions to adapt the bioreactor environment to the cells changing needs during different growth phases, maximizing cell yield

- Machine Learning can predict, based on analysis of complex variables, in real-time the conditions needed for maximizing cell yield

Use Case: Clinical Trials

Challenge

- Use DX to optimize clinical trial designs, predict patient recruitment, and analyze trial data more efficiently

Solution

- Deployed AI to analyze clinical trial data and improve patient matching and recruitment

- AI-driven system accelerated trial enrollment and improved trial outcome prediction

Results

- Estimated value generated: $75 million

- Value was achieved through shortened trial durations, improved success rates, and reduced costs associated with trial failure and delays

REDUCED POPULATION HETEROGENEITY
Biomarker verification to reduce variability and increase study power.

PROGNOSTIC ENRICHMENT
Selecting patients more likely to have measurable clinical endpoints.

PREDICTIVE ENRICHMENT
Identifying patients more likely to respond to the treatment.

ML and DL methods can be applied to mine, analyse and interpret multiple data sources, including EHRs, medical imaging, and 'omics' data.

Source: Deloitte analysis.

Source: Deloitte (https://www2.deloitte.com/us/en/insights/industry/life-sciences/artificial-intelligence-in-clinical-trials.html)

Use Case: Predictive Maintenance
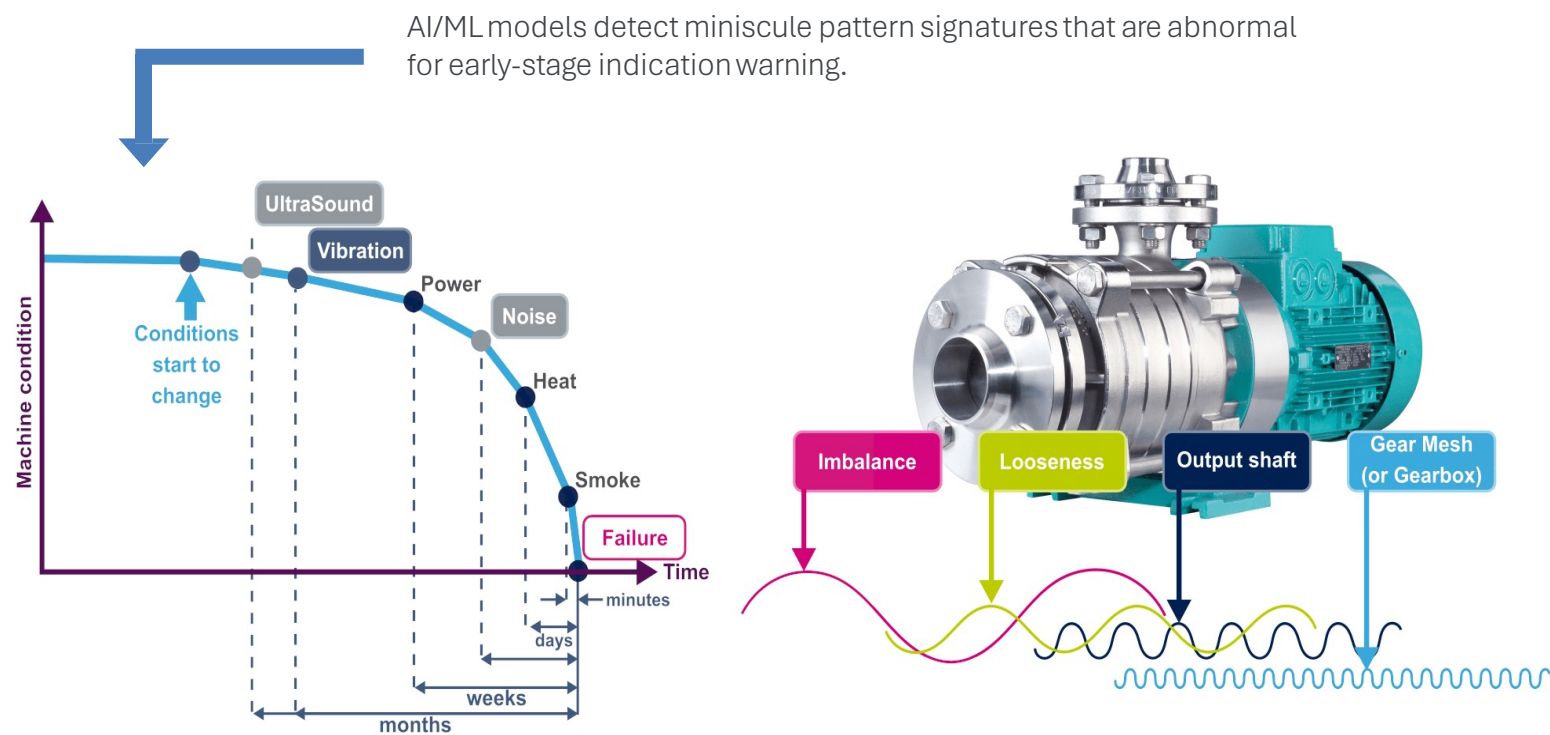
Transform maintenance with the ability to predict anomalies and reduce or eliminate unscheduled maintenance events.

AI/ML models detect miniscule pattern signatures that are abnormal for early-stage indication warning.

AI detects complex patterns and combinations of variables that cannot be detected by humans or seen in any single variable trend.

A Unified Operation

AI and Digital Twins facilitate better collaboration among departments and stakeholders by offering a unified platform for data exchange and decision-making, marking a significant improvement in pharmaceutical manufacturing that fosters efficiency, flexibility, and competitiveness in a challenging market.

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A Digital Platform

Building a data-driven infrastructure

UNS: A New Paradigm for Data-Driven Ops

- A Unified Namespace is the foundation of a data-driven approach

- Publish/Subscribe approach: all devices are a node in the ecosystem

  - Nodes, PLCs, even historians, are no longer the Centerpiece of the architecture, but rather the Unified Namespace (UNS).

  - They're able to produce and consume information freely using the Same Central Source the Unified Namespace (UNS).

- Enabling agile DX: less costly, more straightforward to implement and maintain
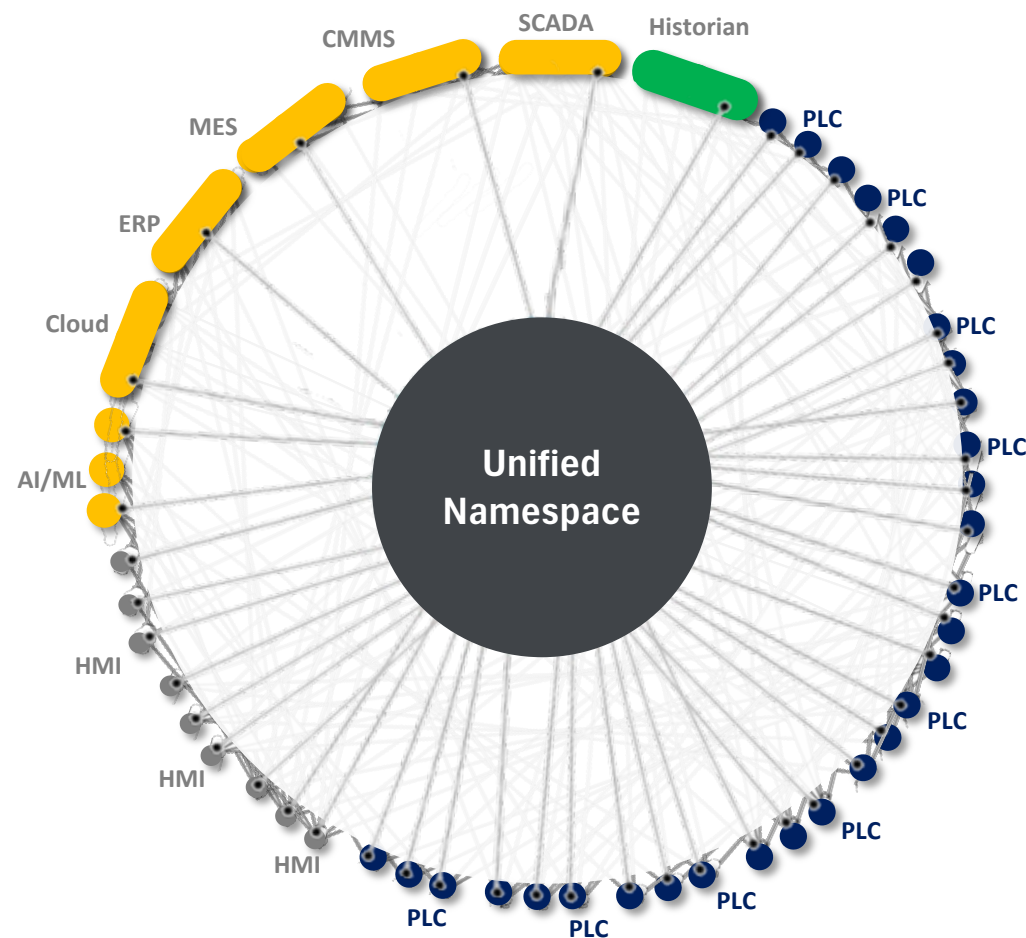
A Complete Digital Platform

The Bio Sciences digital platform is an end-to-end, compliant platform from data collection, control and visualization to full quality, process orchestration and events with integrated data in a unified name space with built-in analytics

Completely integrated data

Scalable cloud-deployed services

Analytics

Unified Data

Process Orchestration

Quality

EEMS

Control

On-Premises control and high-availability

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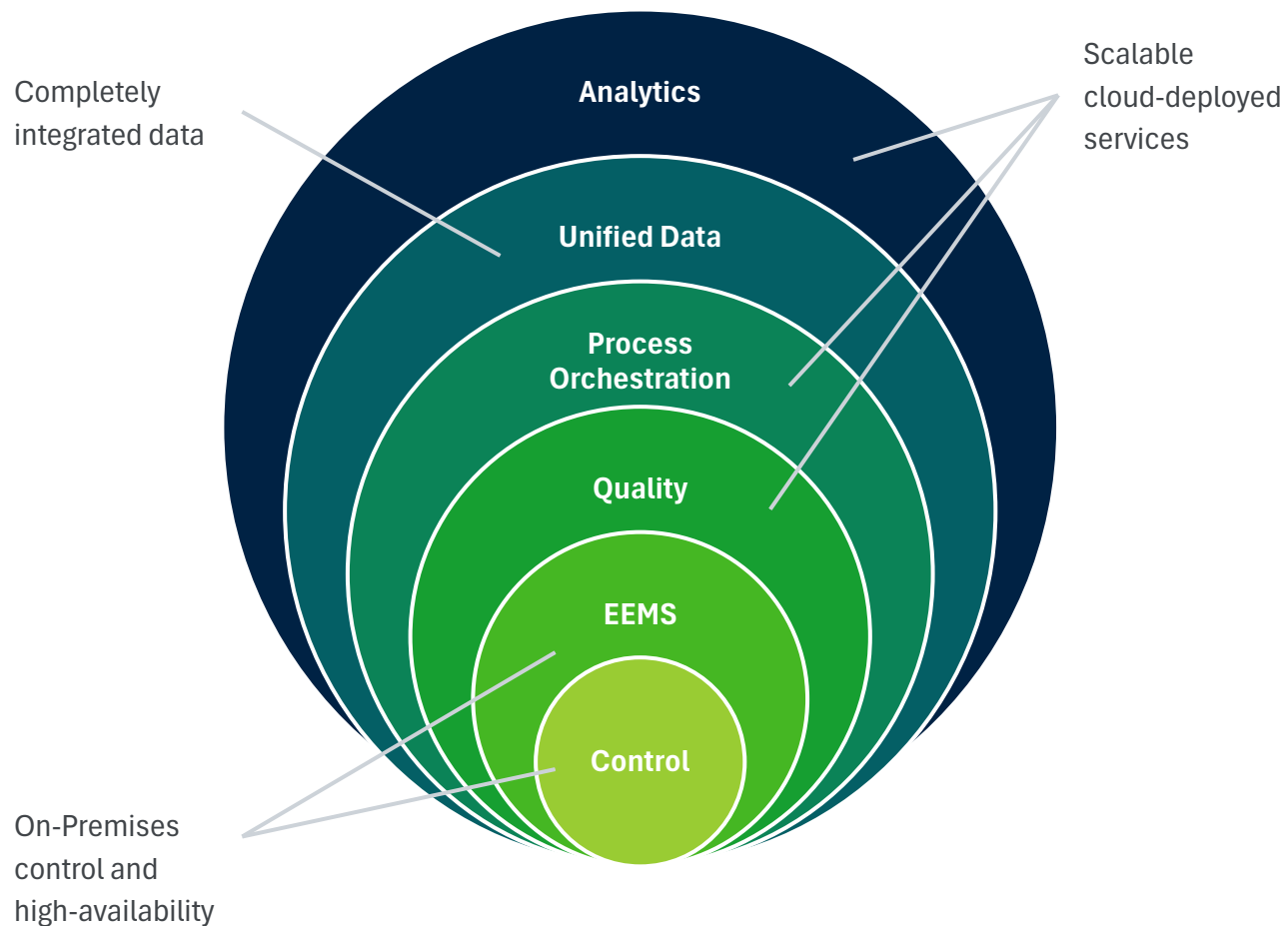
A Digital Platform Connects Your Entire Enterprise

Analytics

Unified Data

Process Orchestratio n

Quality

EEMS

Co ntr ol

Common, secure and collaborative platform for process and knowledge management across all Life Sciences operations

Clinical and Research

Cell and Seed Growth

At -Scale Manufacturing
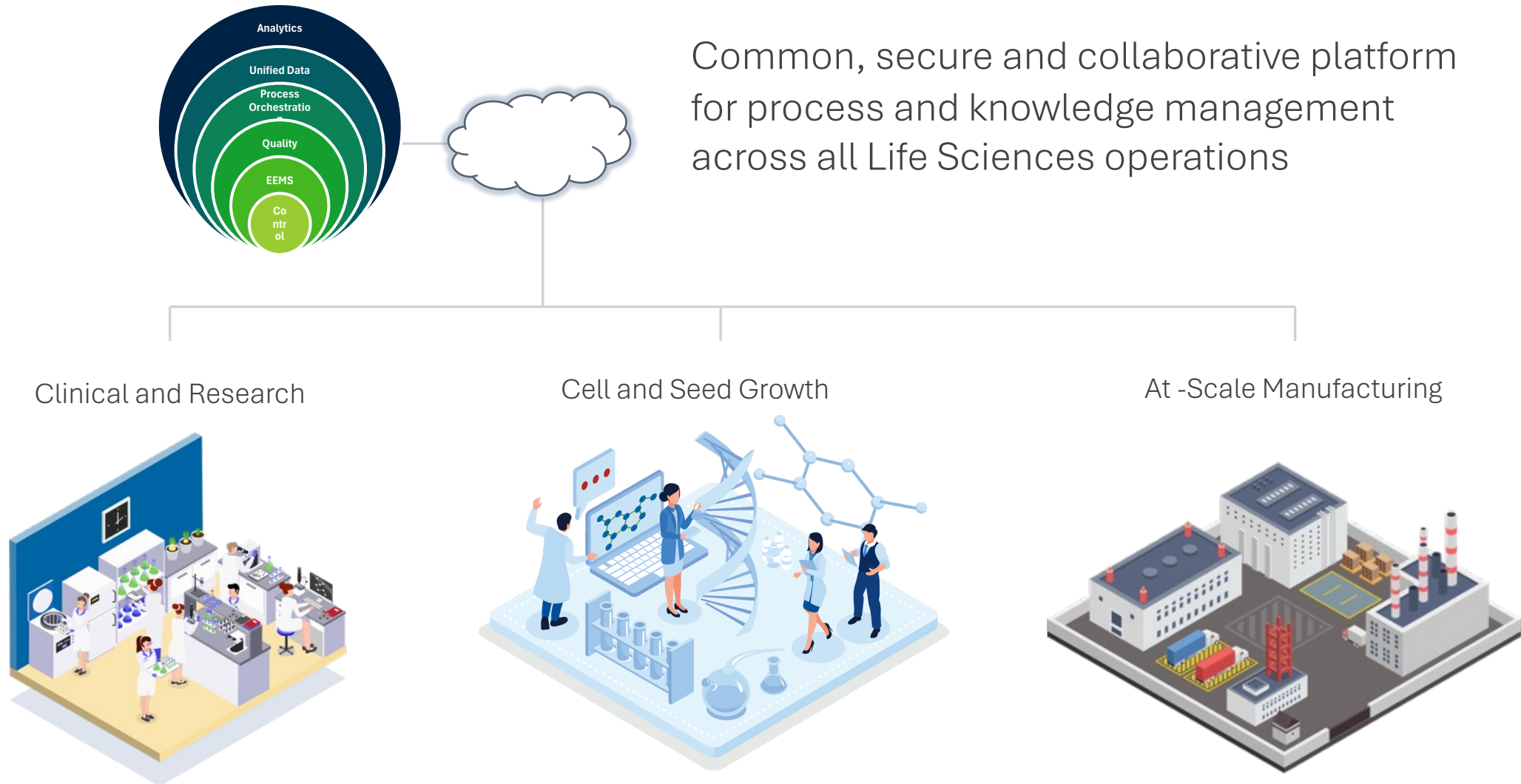
About Us

Your Digital Transformation partner

Delivering on the Promise of Digital Transformation (DX)

We help you run more efficiently and effectively through the deployment of integrated systems that harness the power of automation, analytics, and AI.

InflexionPoint DX Framework

Automation & Control	SCADA / MES Intelligence	Analytics and AI / ML	Remote Management	Cybersecurity and Infrastructure

Data

People	Processes	Equipment
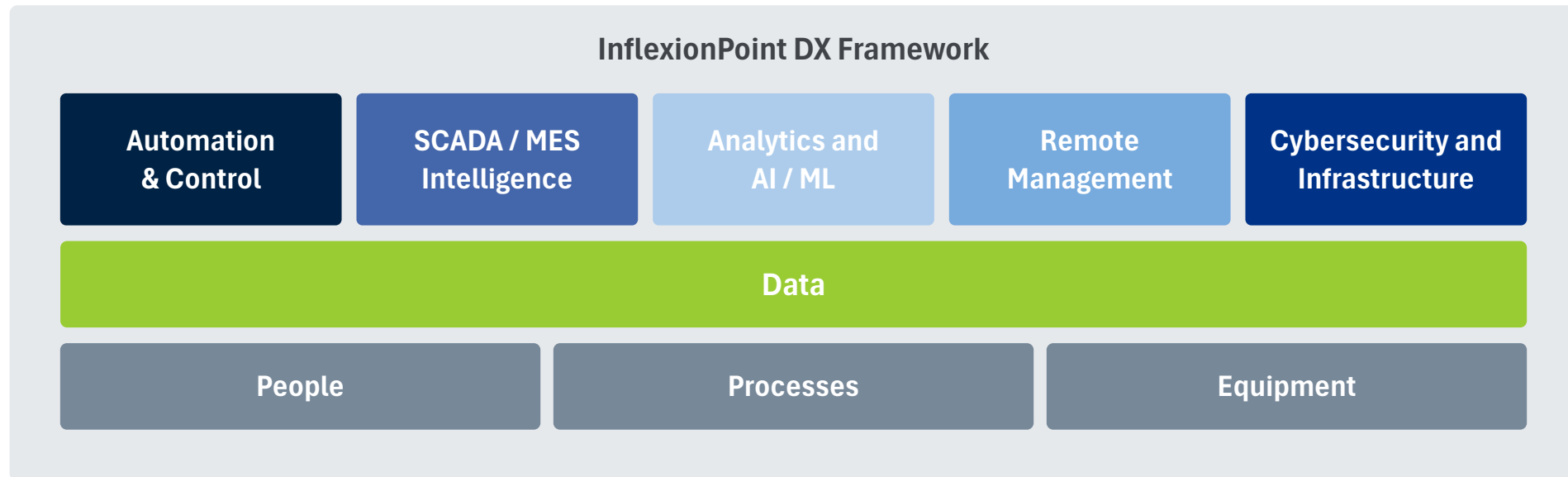
Design. Build. Manage. We work with you every step of the way, from initial requirements through design, implementation, and management.

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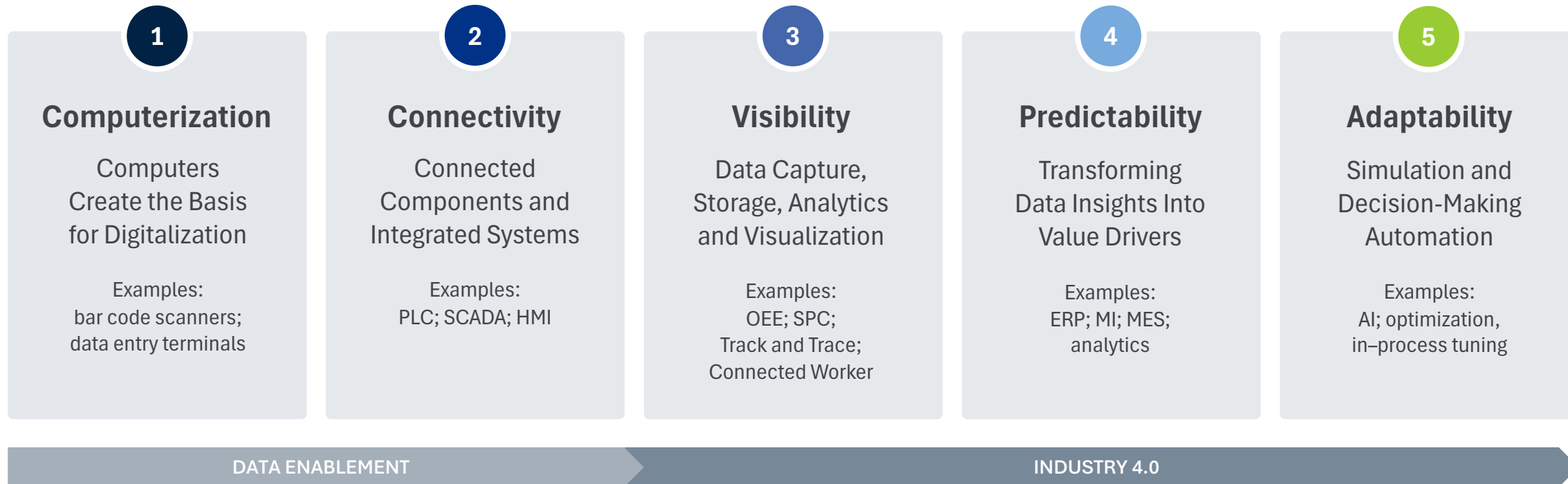# Your Goals. Our Guidance. Shared Success.

Digital transformation is the culmination of a multi-stage journey.

We pursue an incremental approach that fits your company's capabilities and goals.

1	**2**	**3**	**4**	**5**
Computerization	**Connectivity**	**Visibility**	**Predictability**	**Adaptability**
Computers Create the Basis for Digitalization	Connected Components and Integrated Systems	Data Capture, Storage, Analytics and Visualization	Transforming Data Insights Into Value Drivers	Simulation and Decision-Making Automation
Examples: bar code scanners; data entry terminals	Examples: PLC; SCADA; HMI	Examples: OEE; SPC; Track and Trace; Connected Worker	Examples: ERP; MI; MES; analytics	Examples: AI; optimization, in–process tuning

DATA ENABLEMENT → INDUSTRY 4.0

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Serving Life-Sciences Leaders for 40 Years

For 40 years we have served leading companies in life sciences, providing cutting-edge solutions that harness the power of automation and data to accelerate operations.

Digital Transformation Discovery & Assessment

- Our experts help you create a clear picture of where you are today and where you want to be

- We work together to develop the strategies to achieve your goals with a minimum of cost and risk

- The result: a custom roadmap for DX implementation at your company

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Thank You

Questions and Discussion