AVEVAWORLD

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APRIL 9, 2025

AVEVA & xLM:

CONNECT as a platform for Continuous Intelligent Validation

Pharma Industry Roadmap

SESS-270

Todd Brown – AVEVA Nagesh Nama – ValiMation, xLM



APRIL 2025

CONNECT as a platform for Continuous Intelligent Validation – Pharma Industry Roadmap

Todd Brown – VP, Industrial Platform Portfolio

Nagesh Nama - CEO, xLM



Todd Brown

VP, Industrial Platform Portfolio **AVEVA**

With 25-years' experience in operations industrial data, Todd leads the CONNECT industrial platform portfolio team at AVEVA.

Nagesh Nama

CEO

xLM

Mr. Nama is a distinguished entrepreneur with over three decades of experience in the technology and life sciences sectors. He currently serves as the chief executive officer of xLM in Jacksonville, Florida, a role he has held since 2015.

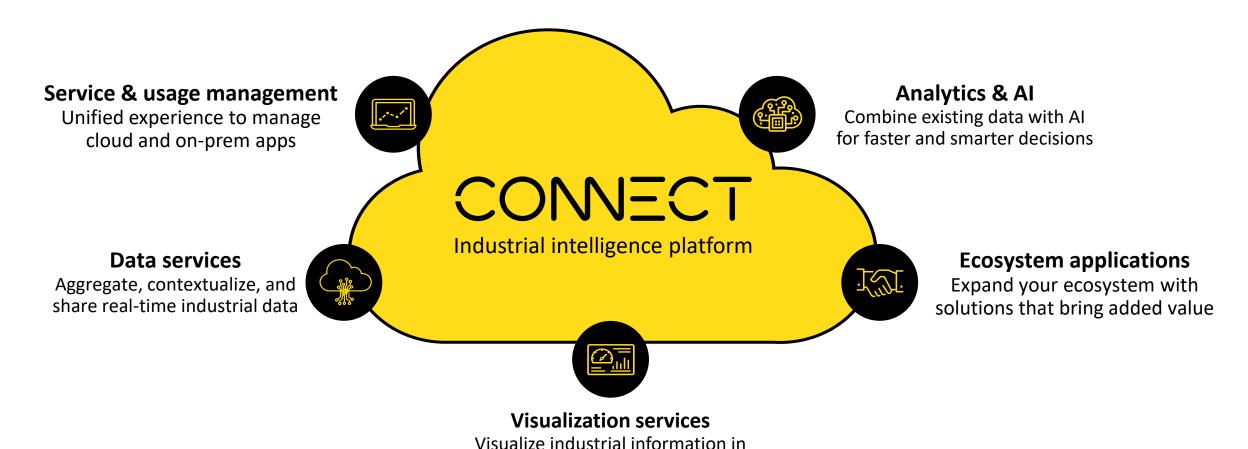


Agenda

- CONNECT platform overview
- CONNECT roadmap themes
 - Hybrid
 - Enterprise Insights
 - Ecosystem
 - Industrial Digital Twin
- Pharma / Life Sciences GxP Roadmap
- xLM continuous validation & demo
- Q&A



Open and neutral, providing rich insights for your unified industrial ecosystem

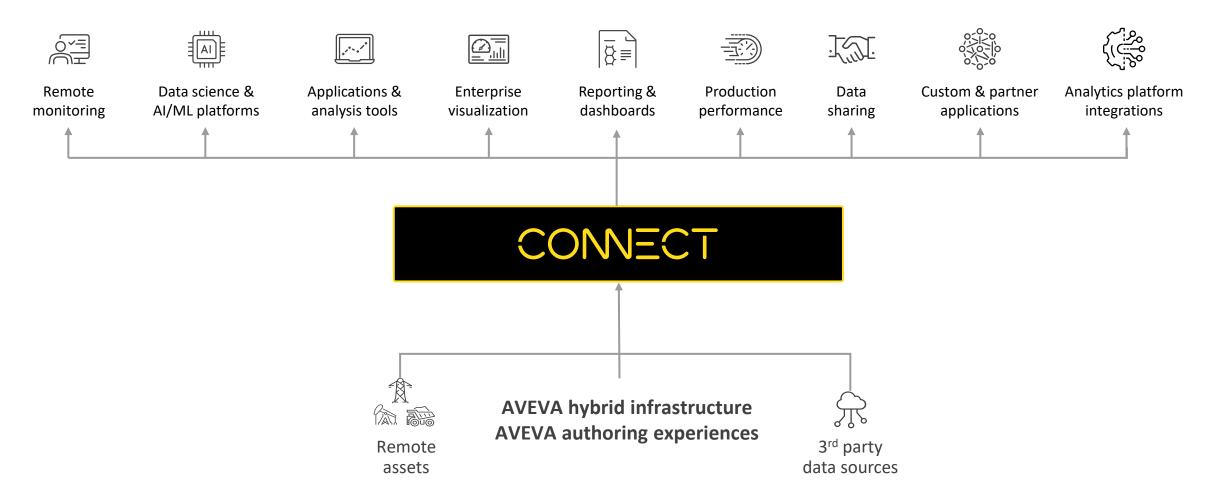


a way that is easy to understand

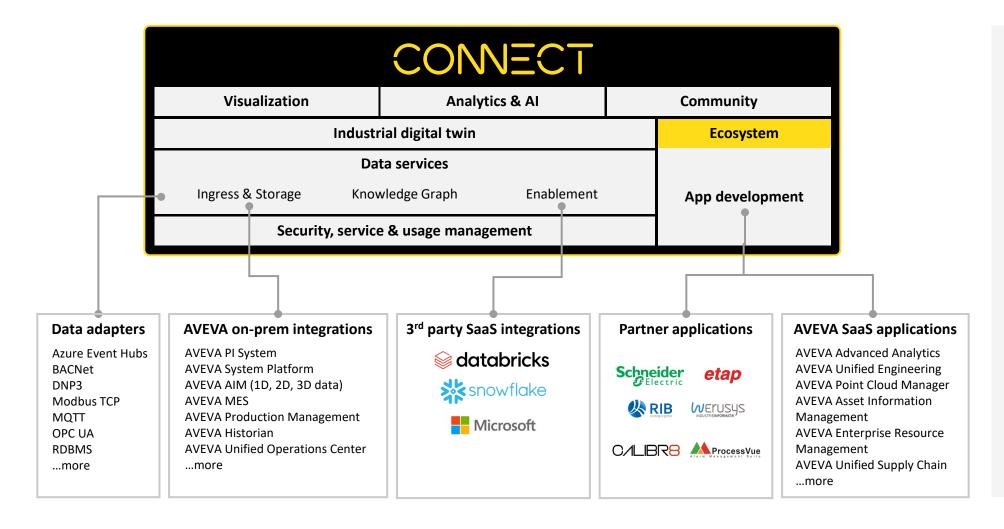


Industrial intelligence platform

Providing hybrid solutions to accelerate new value creation for AVEVA customers



Extending customer value with hybrid and ecosystem capabilities



The industrial intelligence platform with everything you need:

- Aggregate data from many sources across the enterprise
- Access and add new capabilities
- Share data with other cloud-based partners
- Manage and extend on-premises systems in a hybrid configuration
- Leverage the industrial ecosystem





CONNECT roadmap themes



<u>Hybrid</u>: Extend the value for AVEVA's existing customers

Secure, rapid connectivity – powerful new use cases System of record for industrial data, apps, & data science capabilities



Enterprise insights: From enterprise data to industrial insights

Powerful analytics and AI models driving operations improvements Visually relate data in context and expedite analysis with an AI Assistant



Ecosystem: Drive digital transformation

Leverage a network of partner applications and services Flexibly use, monitor, and provision AVEVA capabilities



Industrial digital twin: Bridge engineering & operations context

Shared version of the truth for analytics, visualization, and Al Enhance visibility, consistency, and insights across operations

CONNECT ROADMAP THEME

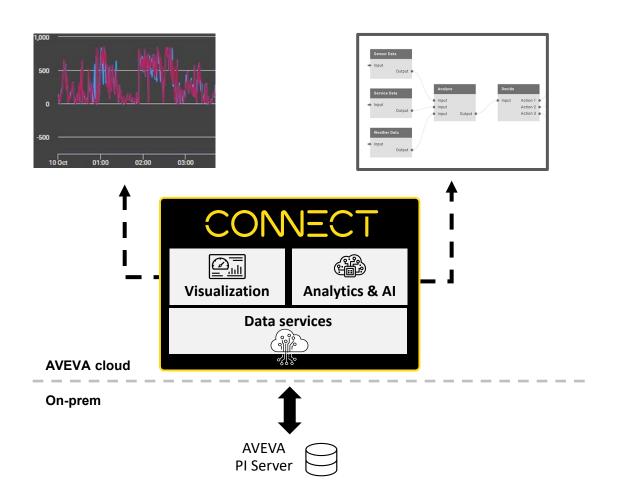


Extend the value for AVEVA's existing industrial customers



CONNECT for AVEVA PI Data Infrastructure

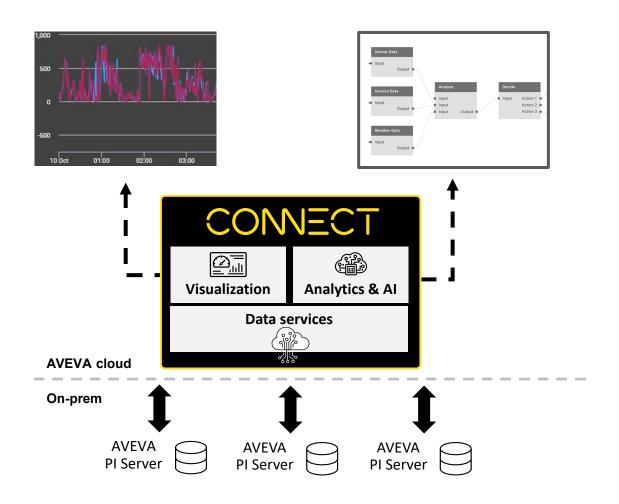
Bring results back on-prem from CONNECT in a safe, secure, robust manner



- Predicting quality and throughput
- Optimizing production in real time
- Optimizing for energy efficiency
- Results on-prem in operational context

CONNECT for AVEVA PI Data Infrastructure

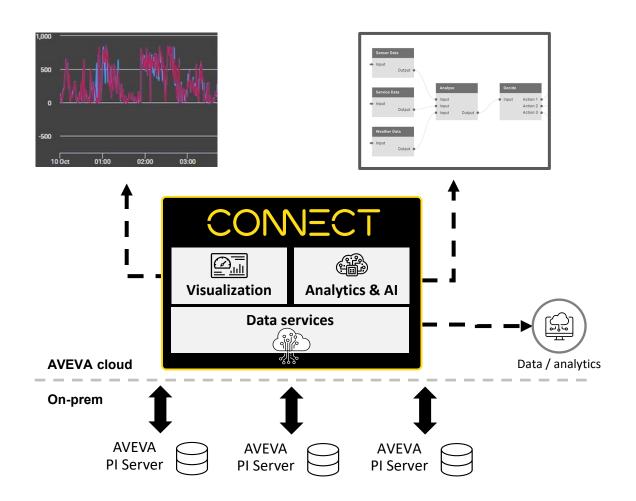
Easily integrate multi-site data at scale



- Predicting quality and throughput
- Optimizing production in real time
- Optimizing for energy efficiency
- Results on-prem in operational context
- Reducing TCO by replacing regional servers

CONNECT for AVEVA PI Data Infrastructure

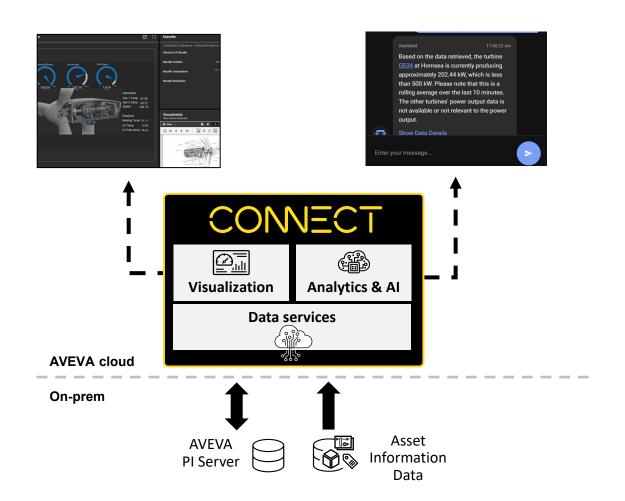
Curate data in context and share with 3rd party analytic and data vendors



- Predicting quality and throughput
- Optimizing production in real time
- Optimizing for energy efficiency
- Results on-prem in operational context
- Reducing TCO by replacing regional servers
- Easily curate data in context at scale

CONNECT for AVEVA PI Data Infrastructure & AVEVA Asset Information Management

Easily integrate operations and asset information



- Predicting quality and throughput
- Optimizing production in real time
- Optimizing for energy efficiency
- Results on-prem in operational context
- Reducing TCO by replacing regional servers
- Easily curate data in context at scale
- Answering questions offering new insights across information boundaries







Deliver enterprise industrial insights that deliver more value

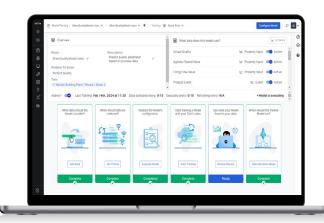
Enterprise Insights

CONNECT visualization



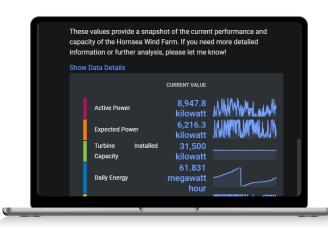
Visualization of enterprise data in context

AVEVA Advanced Analytics



Powerful analytics and AI models driving operations improvements

CONNECT Industrial AI Assistant



Natural language interface for your enterprise data



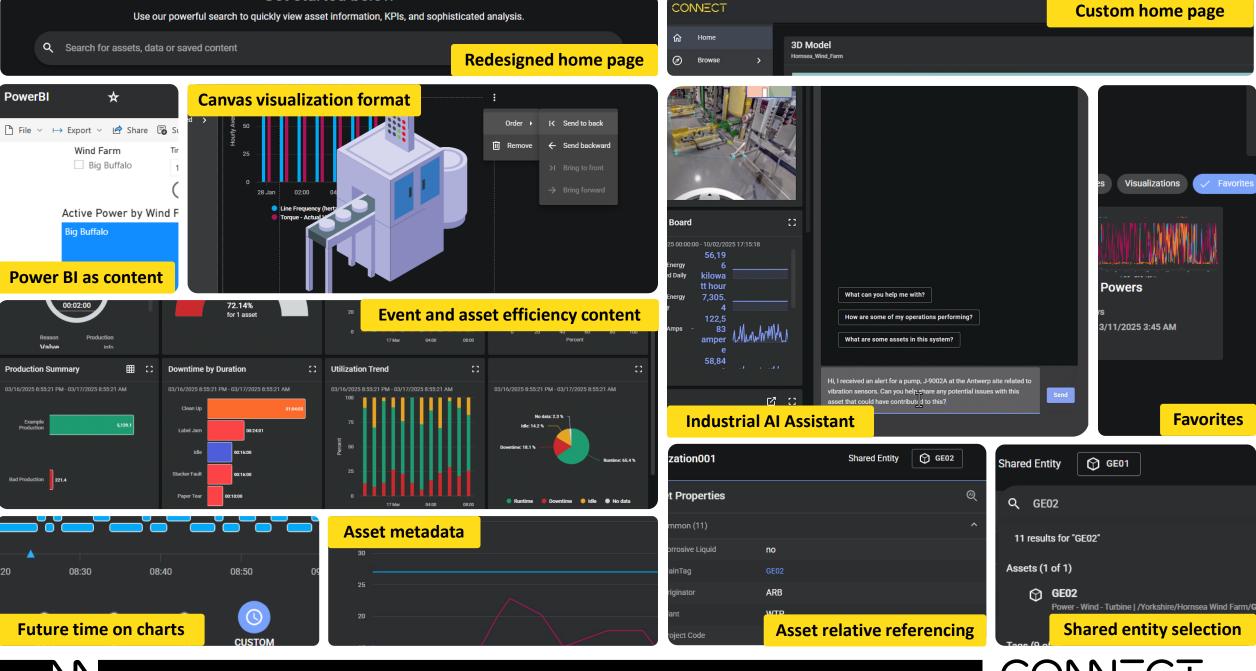
CONNECT visualization



Visualize complex relationships and data-driven insights in a way that is easy to understand

- Relate disparate data sources & systems in context to each other
- Gather insights between data sources and across data types quickly and easily
- Expedite analysis using an Industrial AI Assistant to answer natural language questions
- Share actionable information with operations, reliability, business, and other teams, anywhere through a browser

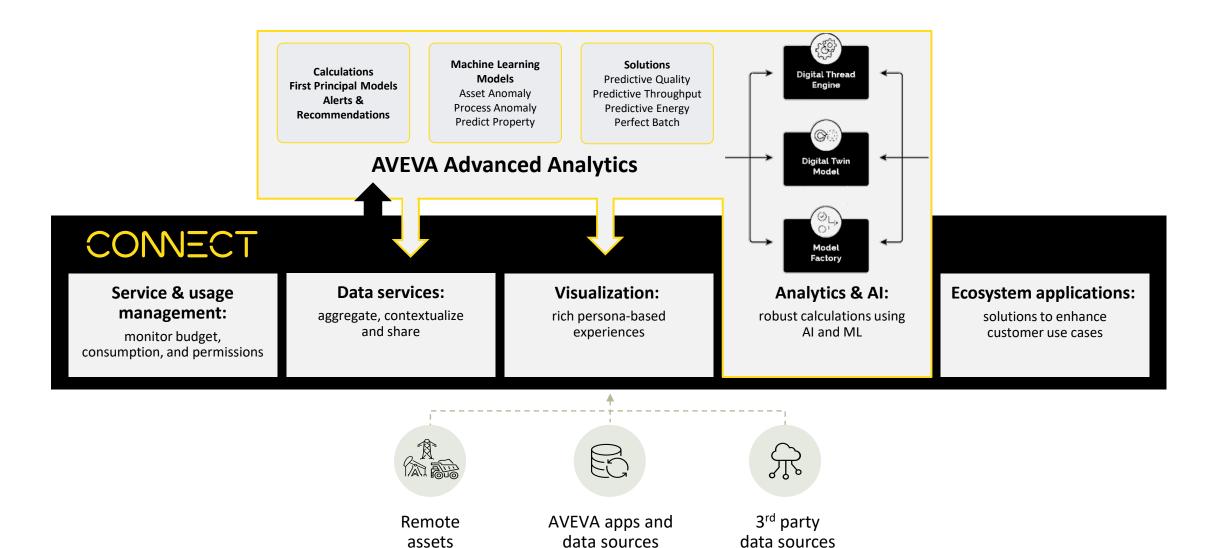




OCI Started Delow



Connect AI with all industrial data and visualization



Al-driven optimization for industrial excellence

Process Optimization

Perfect Energy

Operate at the sweet spot of production and energy consumption

Perfect Production

Automate investigations and understand performance drivers with ML

Perfect Quality

Reduce variability, eliminate losses, and improve operational flexibility

Perfect Batch

Continuously evaluate batch performance and automate actions

AVEVA Advanced Analytics

Asset Optimization

Uptime Optimization

Real-time alerts and recommendations to avoid downtime events

Throughput Optimization

Maximize production output on a per-product and per-asset basis

Asset Reliability

Predict and prevent common failure modes at scale

Asset Life

Maximize serviceable life and proactively manage failure risks at scale

Perfect Centerline

Identify optimal operating conditions for the best performance, yield, or quality

Asset Anomaly Detection

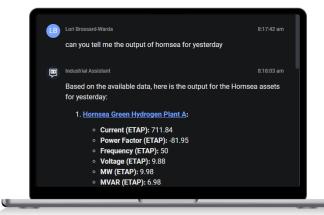
Detect asset anomalies in real-time, prioritize by impact, enable early intervention



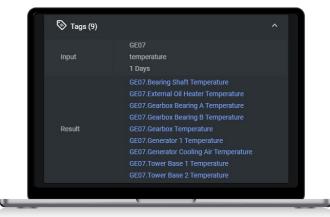
Industrial Al Assistant

Natural language interface to your data in CONNECT

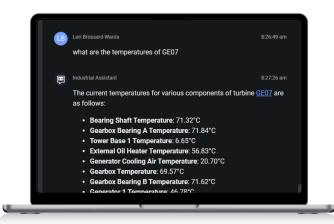
Natural language interface



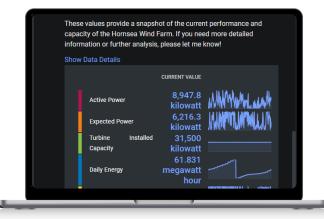
Citations show work (transparency & traceability)



Content search & summarization



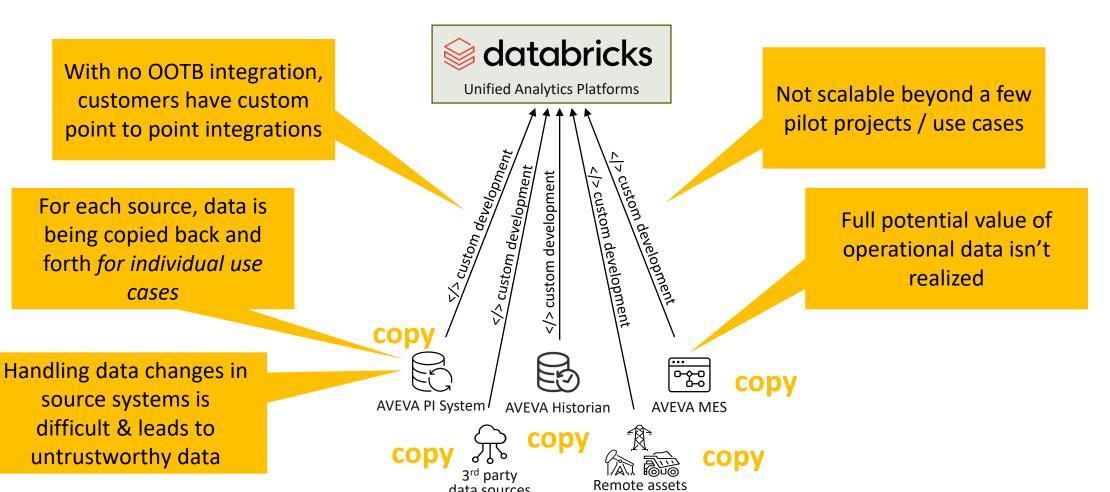
Generate dashboards & charts inline







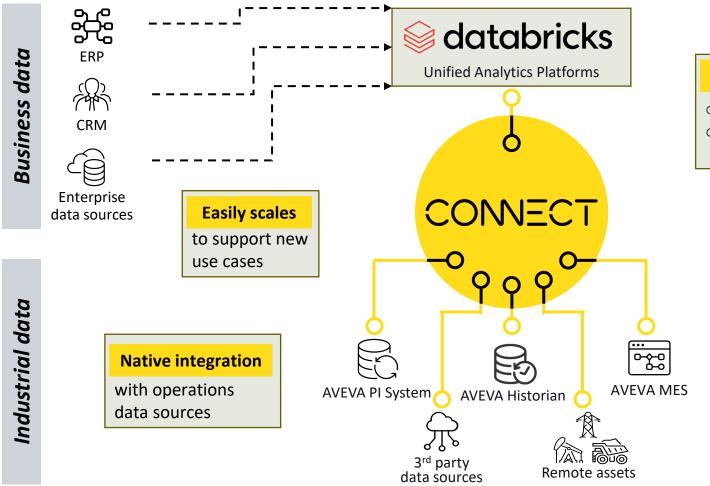
Past: Custom fragmented solutions that aren't scalable





Today: Live industrial data for data science

Authoritative, high quality, contextualized live sharing of data between OT and IT environments



Out-of-the-box integration

- No custom development
- No maintenance by end customer

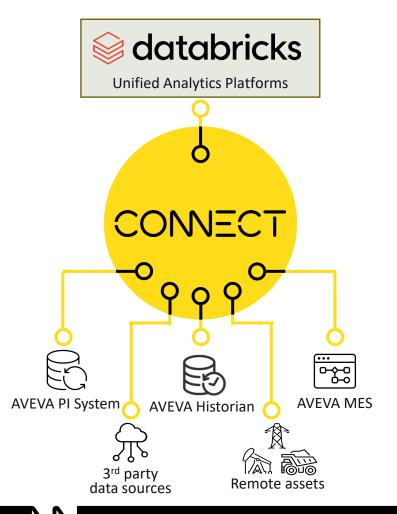
Aggregated industrial data

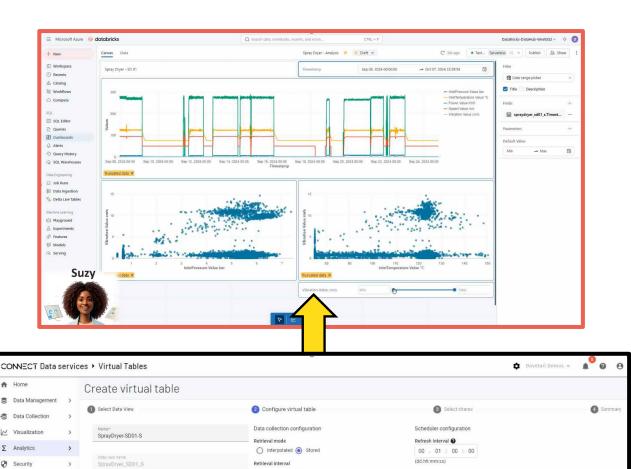
- Maintain and augment contextualization of data across sites and sources
- Ensure accurate capture of updates and changes to the system of record
- Results and insights return to OT environments

Today: Live industrial data for data science

Authoritative, high quality, contextualized live sharing of data between OT and IT environments

Support





Time-Extending Window

Data Scientist



Data Analyst



Data Architect



CONNECT ROADMAP THEME



Industrial Digital Twin 🚟

Harmonize siloed engineering and operations data together for a shared version of industrial truth

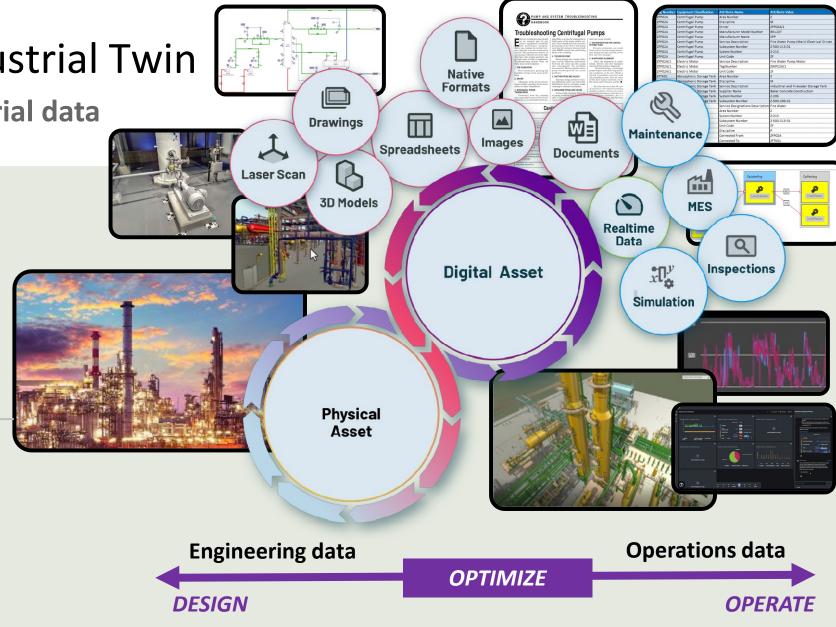


AVEVA's Digital Industrial Twin

A map for ALL YOUR industrial data

AVEVA'S Industrial Twin is a digital representation, which harmonizes data from a variety of systems/sources, in context to form a digital representation of a system, plant or piece of equipment and includes the visualization of the information.

Digital twins can help many kinds of organizations rapidly access information and simulate real situations and their outcomes, ultimately allowing them to make better decisions.





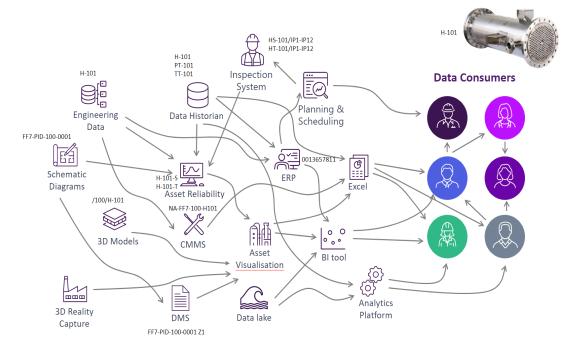
Digital twins are a hard problem The data challenge: industrial data trapped in silos

- Increasing data over time + documents from 1997
- Different representations across different silos
- Data conflicts

- Lack of trust in the data
- Scale up: 16M assets & 40B relationships
- Scale down: 100 assets
- No info. standards in place
- Varying rates of change

1D

 Resource intensive projects with specialized expertise required

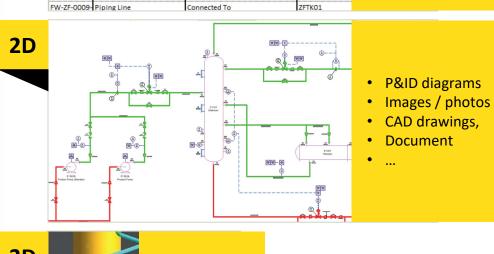


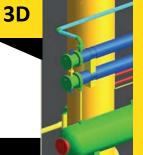
Many data silos with different representations of the same equipment

| Tag Number | Equipment Classification | Attribute Name | Attribute Value |
|-------------|--------------------------|----------------------------------|-----------------|
| ZFP02A | Centrifugal Pump | Area Number | Z |
| ZFP02A | Centrifugal Pump | Discipline | M |
| ZFP02A | Centrifugal Pump | Driver | ZFP02A/1 |
| ZFP02A | Centrifugal Pump | Manufacturer Model Number | BR12DT |
| ZFP02A | Centrifugal Pump | Manufacturer Name | SPP |
| ZFP02A | Centrifugal Pump | Service Description | Fire Water Pum |
| ZFP02A | Centrifugal Pump | Subsystem Number | Z-500-213-01 |
| ZFP02A | Centrifugal Pump | System Number | Z-213 |
| ZFP02A | Centrifugal Pump | Unit Code | ZF |
| ZFP02A/1 | Electric Motor | Service Description | Fire Water Pum |
| ZFP02A/1 | Electric Motor | Tag Number | ZWP22A/1 |
| ZFP02A/1 | Electric Motor | Unit Code | ZF |
| ZFTK01 | Atmospheric Storage Tank | Area Number | Z |
| ZFTK01 | Atmospheric Storage Tank | Discipline | M |
| ZFTK01 | Atmospheric Storage Tank | Service Description | Industrial and |
| ZFTK01 | Atmospheric Storage Tank | Supplier Name | Baker Concrete |
| ZFTK01 | Atmospheric Storage Tank | System Number | Z-206 |
| ZFTK01 | Atmospheric Storage Tank | Subsystem Number | Z-500-206-01 |
| FW-ZF-0009- | Piping Line | Service Designations Description | Fire Water |
| FW-ZF-0009- | Piping Line | Area Number | Z |
| FW-ZF-0009- | Piping Line | System Number | Z-213 |
| FW-ZF-0009- | Piping Line | Subsystem Number | Z-500-213-01 |
| FW-ZF-0009- | Piping Line | Unit Code | ZF |
| FW-ZF-0009- | Piping Line | Discipline | P |
| FW-ZF-0009- | Piping Line | Connected From | ZFP02A |
| | | | |

Connected To

- Assets / equipment
- Properties
- Material definitions
- Work words
- Quality
- Documents

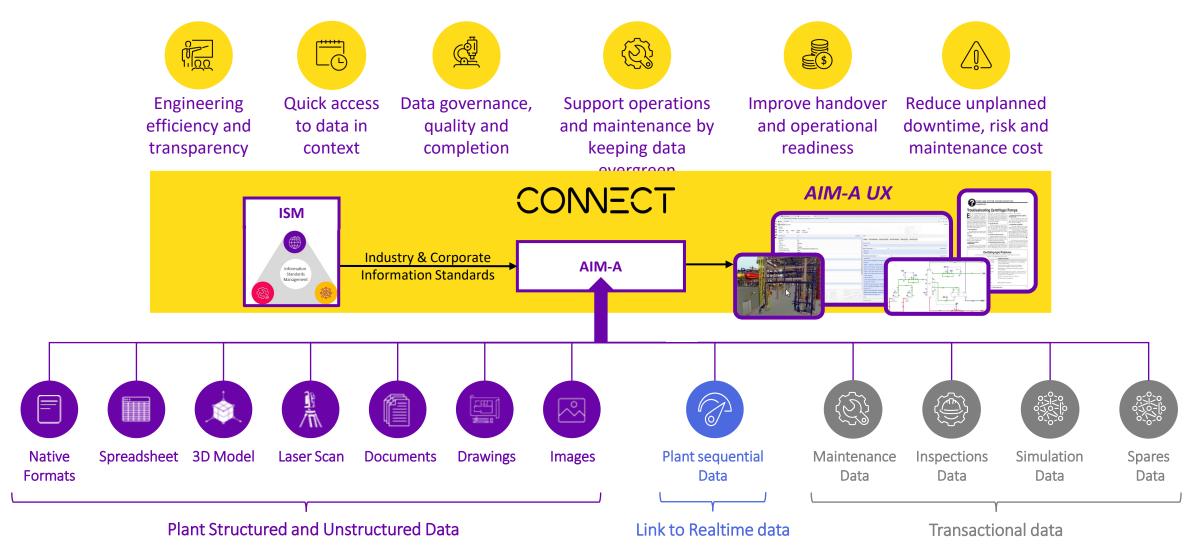




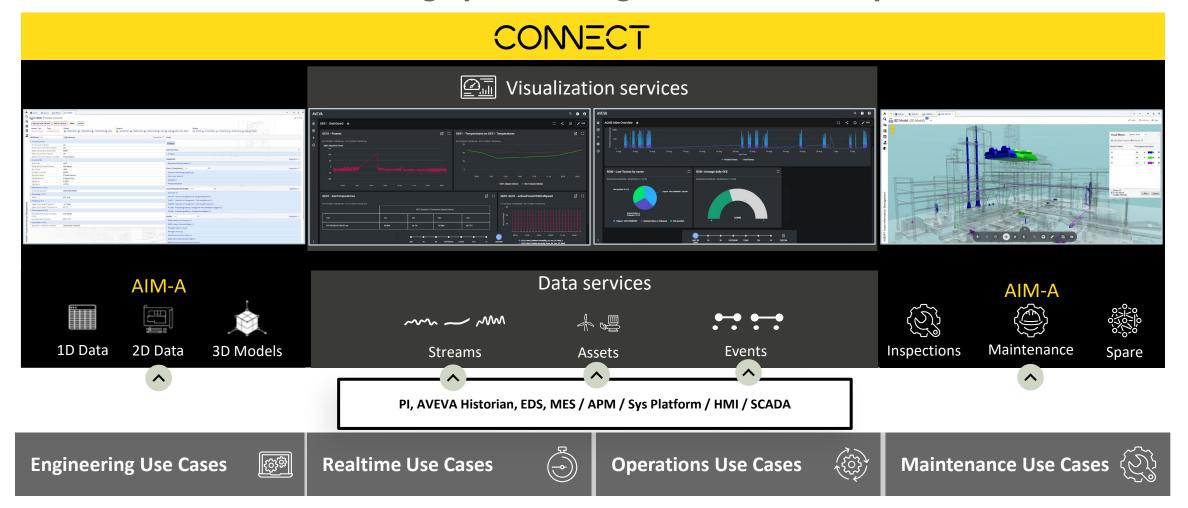
- 3D CAD models
- Laser scans
- Point clouds



AVEVA Asset Information Management (AIM-A)



Leverage your existing investments today



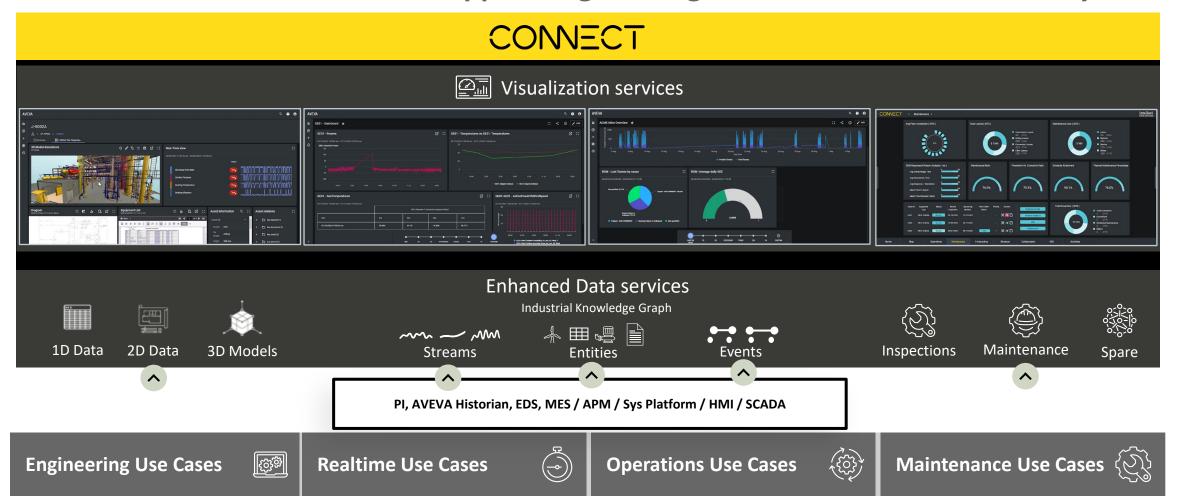


Visualization supports engineering & maintenance data in AIM-A



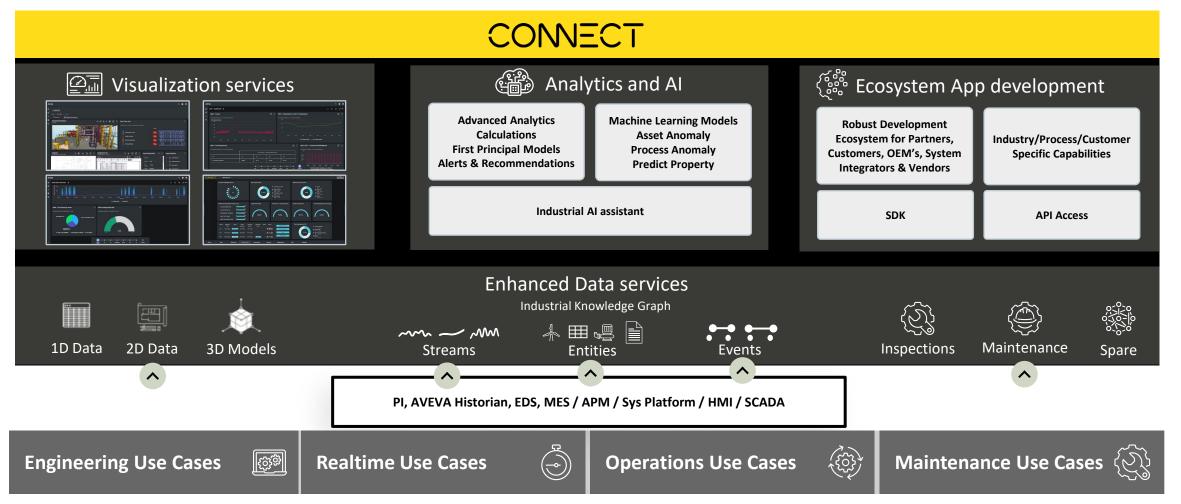


Enhanced data services support engineering & maintenance data natively





Visualization, Analytics, & Ecosystem leverage an AI assisted digital twin



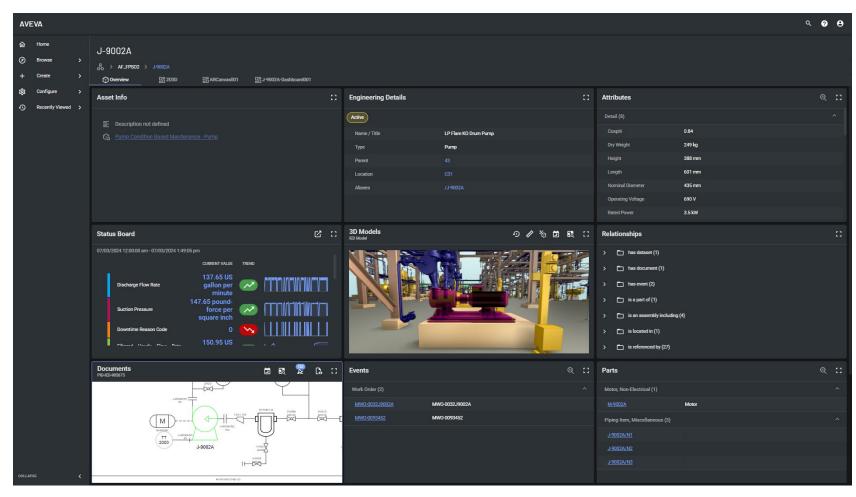


CONNECT: Engineering data visualization

Visualize engineering data from AVEVA Asset Information Management (AIM-A)

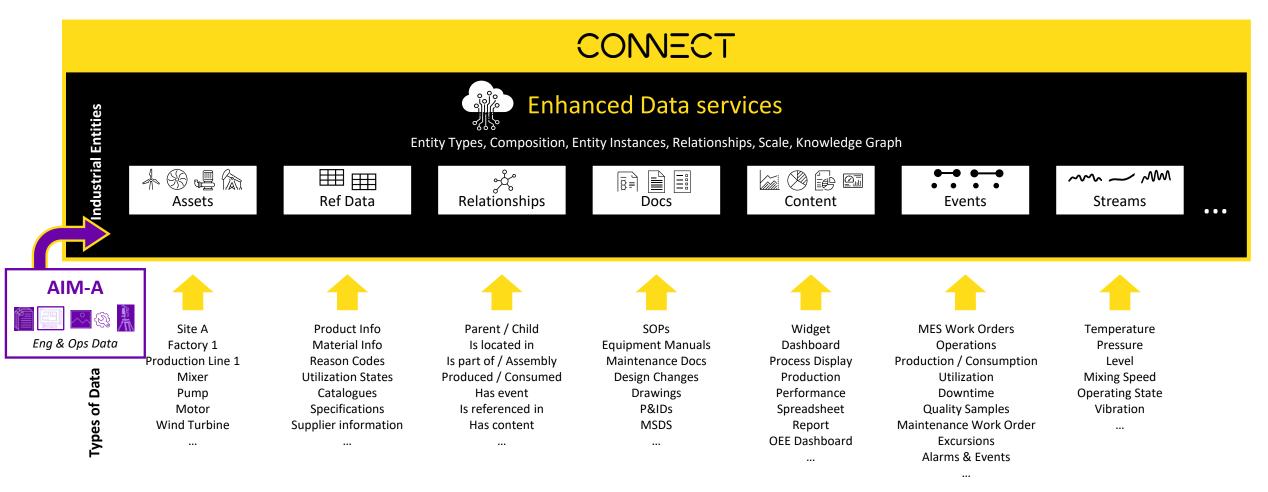
Library of configurable 1D, 2D and 3D data content types:

- 3D viewer
- Doc viewer
- Point cloud viewer
- Properties
- Relationship explorer
- Relationship viewer
- Report viewer
- Microsoft Power BI





CONNECT: Storing broader types of industrial data





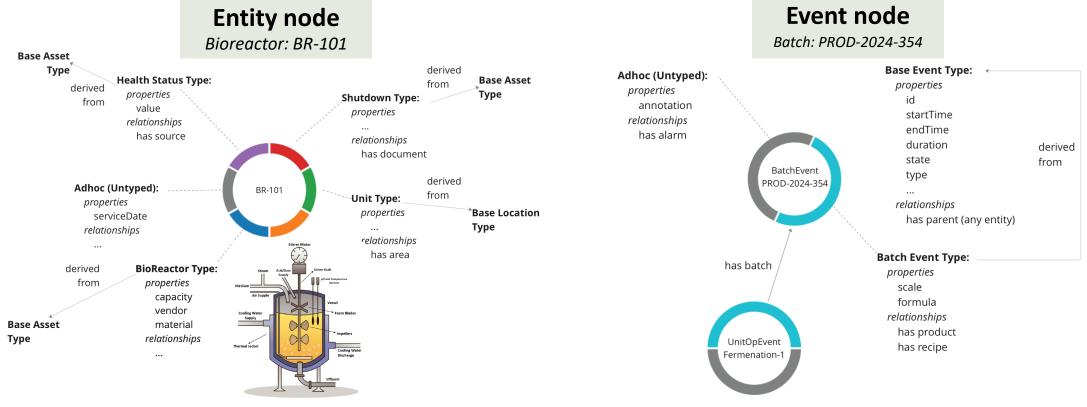
CONNECT: New entity & event store – composition

CONVECT



Enhanced Data services

Entity Types, Composition, Entity Instances, Relationships, Scale, Knowledge Graph



CONNECT: Industrial knowledge graph

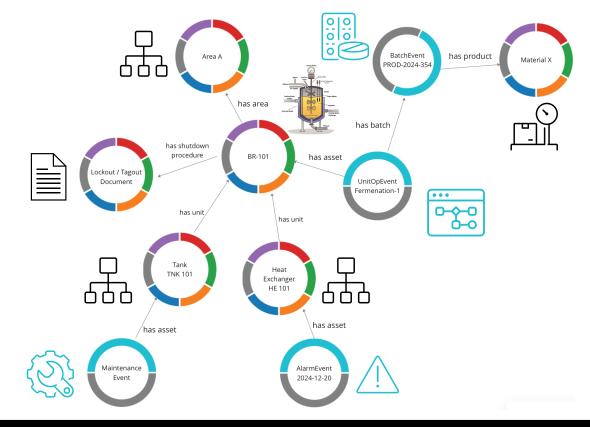
CONVECT



Enhanced Data services

Entity Types, Composition, Entity Instances, Relationships, Scale, Knowledge Graph

Industrial Knowledge Graph



Example knowledge graph questions

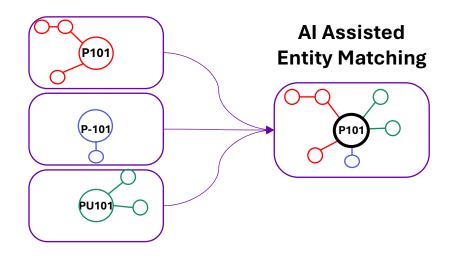
- What are the alarms for all assets and sub-equipment where my batch PROD-2024-354 was running on?
- What are the streams reporting data from the Heat Exchanger HE-101?
- What Piping & Instrumentation (P&ID) documents related to this Heat Exchanger?
- What Isolation does this Heat Exchanger have?
- What are the Safety instructions and any Lockout/Tagout procedures for the Heat Exchanger for Bioreactor 101?
- What batches and equipment had Material X running through it?
- Which equipment across my enterprise do I have maintenance events for Lubrication Oil Pumps and Hydraulic Pump seizures?

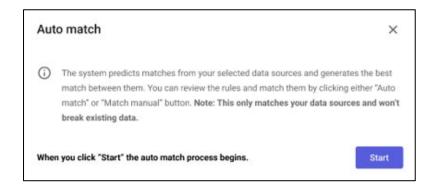


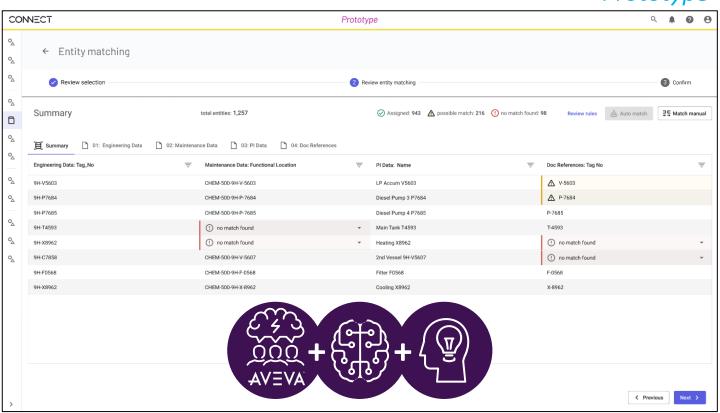
Al assisted data harmonization: Entity matching

CONVECT







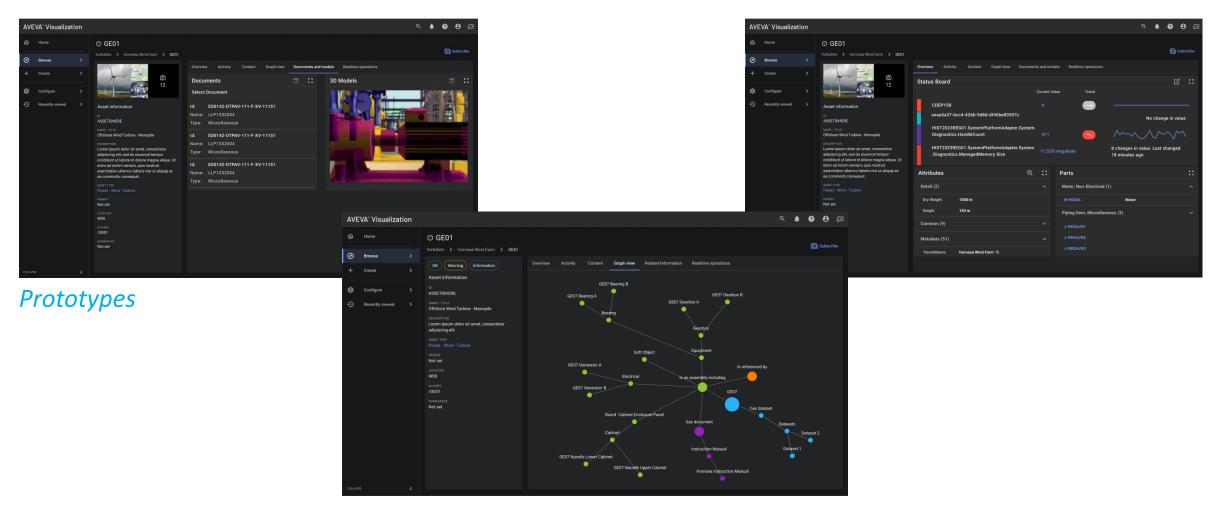


Bringing AVEVA's industrial expertise, AI, and the end user together



CONNECT: Complete harmonized view of your assets

CONVECT





CONNECT

Pharma / Life Sciences GxP Roadmap



Known gaps for leveraging CONNECT for GxP in Life Sciences

 Make appropriate changes to internal processes to incorporate Continuous Validation and become audit ready.

Audit Readiness



 Enhance 21 CFR Part 11 / Annex 11 compliance features into the new CONNECT infrastructure.

Audit Trail



- CONNECT may be updated daily by AVEVA
- Need an industry
 accepted approach to
 support cloud native app
 like CONNECT.

Validation
Approach for cloud SaaS





PI Server / CONNECT



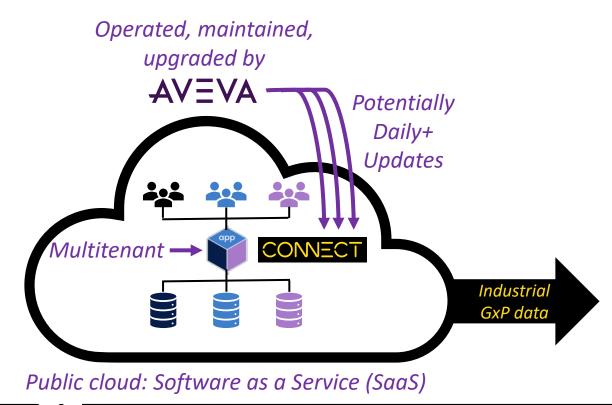


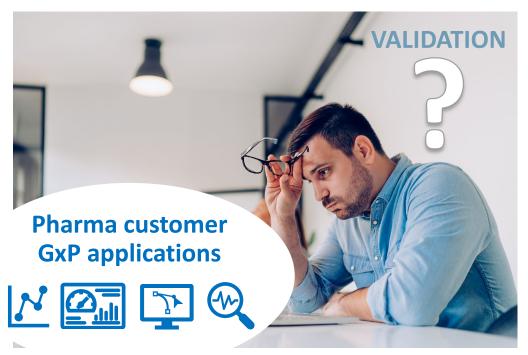
| | AVEVA PI Server | CONNECT industrial platform |
|--|---|--|
| Tenancy model | Single Tenant | Multi-tenant |
| Installed at | On premises: Customer Site / Customer Cloud (IaaS) | AVEVA's <mark>public cloud</mark> on Azure |
| Offering | Perpetual License w/yearly SRP → AVEVA Flex Hybrid | Software as a Service (SaaS) w/AVEVA Flex |
| Developed by | AVEVA | AVEVA |
| Development approaches | Historically waterfall but more agile today, with more automated testing. | Agile, Continuous Integration / Continuous Delivery (CI/CD), Significant Automated Testing |
| Operated by | Customer | AVEVA |
| System maintained & updated by | Customer | AVEVA |
| Frequency of system updates / upgrades | In pharma, usually 6-24 months or longer | Daily+ (could be multiple deployments per day) |
| Configuration maintained & updated by | Customer | Customer |
| Data owned by | Customer | Customer |
| Regulatory Validation Approach | Customer [+ vendor audit] | ? Need to engage & collaborate w/industry |
| Regulatory Accountability | Customer | Customer |



The shared industry problem we need to solve together

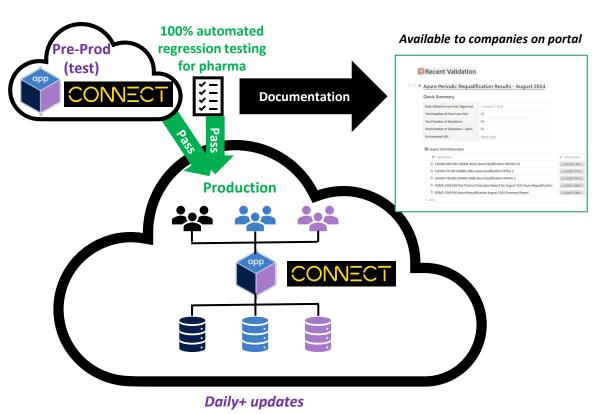
How does a **pharma customer validate** a public vendor multitenant SaaS software offering when the SaaS software is potentially updated with new versions, bug fixes, etc. by the vendor potentially daily or multiple times per day?





What if: AVEVA qualified CONNECT within existing workflows

How does a **pharma customer validate** a public vendor multitenant SaaS software offering when the SaaS software is potentially updated with new versions, bug fixes, etc. by the vendor potentially daily or multiple times per day?



What if AVEVA continuously qualified the system we are operating & maintaining in a partnership with our pharma customers?

- Partner relationship, not vendor relationship
- Integrate pharma GxP automated testing into AVEVA's existing automated testing & deployment pipelines.
- 100% regression testing in Pre-Prod testing environment before every deployment to Production. If tests fail, the changes do NOT get pushed to production, by design.
- Automated validation documentation (including executed test results) must be accessible to pharma customers for every version after the system is initially validated.
- Pharma customers get faster innovation AND increased compliance AND increased data integrity.



Releasing more frequently and with greater stability



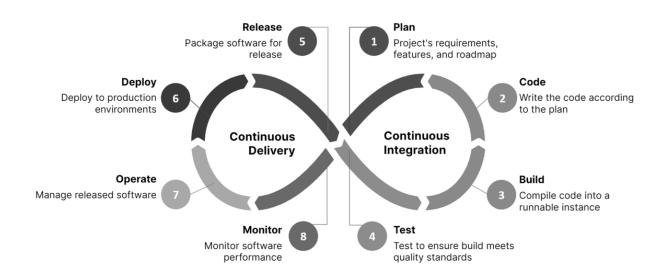
The first sentence in the introduction of our internal *CONNECT release procedure*:

"Successful cloud computing companies deliver software orders of magnitude more frequently than their peers.

Companies like Capital One deploy 50 times per day and companies like Amazon, Google and Netflix deploy thousands of times per day. And they do so while achieving greater stability."

Why release so frequently?





- Always Up-to-Date: New features delivered fast no waiting for major releases.
- ** Fast Bug Fixes: Issues are resolved quickly, often before you even notice them.
- **Stronger Security:** Security patches deployed rapidly to protect your data.
- Smooth, Stable Experience: Smaller, safer updates with minimal disruption; greater stability.

- **Built Around You:** Product evolves with your real-world usage and feedback.
- Less Downtime, Faster Adoption: Seamless updates no more scheduled maintenance delays, results in faster customer adoption at scale.
- **Compliance Confidence:** Ongoing alignment with security and regulatory standards.



Releasing more frequently and with greater stability (+ validation)



Continuous Integration

- Continuous integration (CI) is a development practice that requires developers to integrate code into a shared version-controlled repository several times a day.
- Each check-in is then verified by an automated build, allowing teams to detect problems early.



Continuous Delivery

Continuous delivery (CD)
 automates application
 delivery to selected
 environments, including
 production, development,
 and testing environments.
 CD may execute additional
 tests.



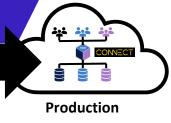
Continuous Validation

Continuous validation (CV)
 adds an additional output to
 the pipeline - a Validation
 Package that bundles up all
 the evidence required for
 GxP compliance. Also,
 provides a larger validation
 package based on Connect
 QMS.

NEW PROPOSED

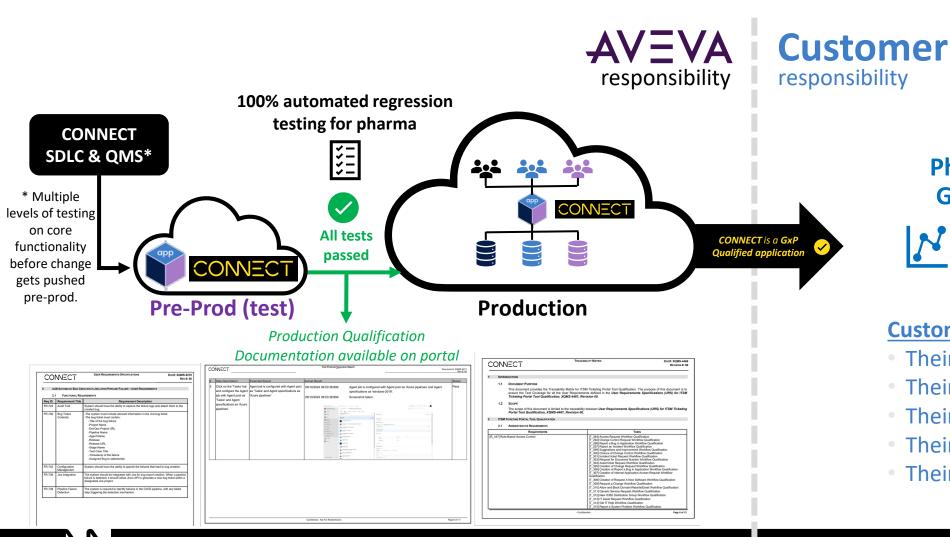


CI/CD/CV Pipeline



A partnership with shared responsibilities





Pharma customer **GxP** applications









Customer validates:

- Their CONNECT tenancy
- Their configuration & data
- Their data connections
- Their data integrations
- Their GxP applications



xLM demo

Nagesh Nama – CEO xLM





Who are we?



Established in 1996 with a focus on providing software products, managed services and compliance solutions to clients in North & South America, Europe, Asia and Australia.

Expertise

- GxP Continuous Validation
- cDI Continuous Data Integrity
- cAl Continuous Intelligence



Serving Top Fortune 500 Pharmaceutical Biotech and Medical Devices Companies.

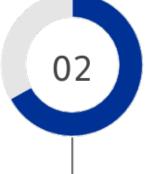


What is Continuous Intelligent Validation (cIV)?





Innovative Al Integration



Elevating Testing Standards

We aim to set new standards in automated testing by using advanced AI to enhance test coverage, reduce false results, and adapt easily to changing environments.



10X Mantra





Why cIV?





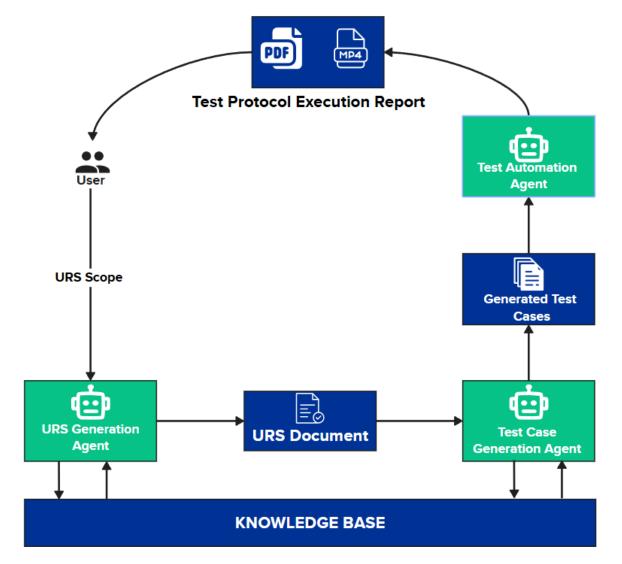


Architecture



cIV's three key components:

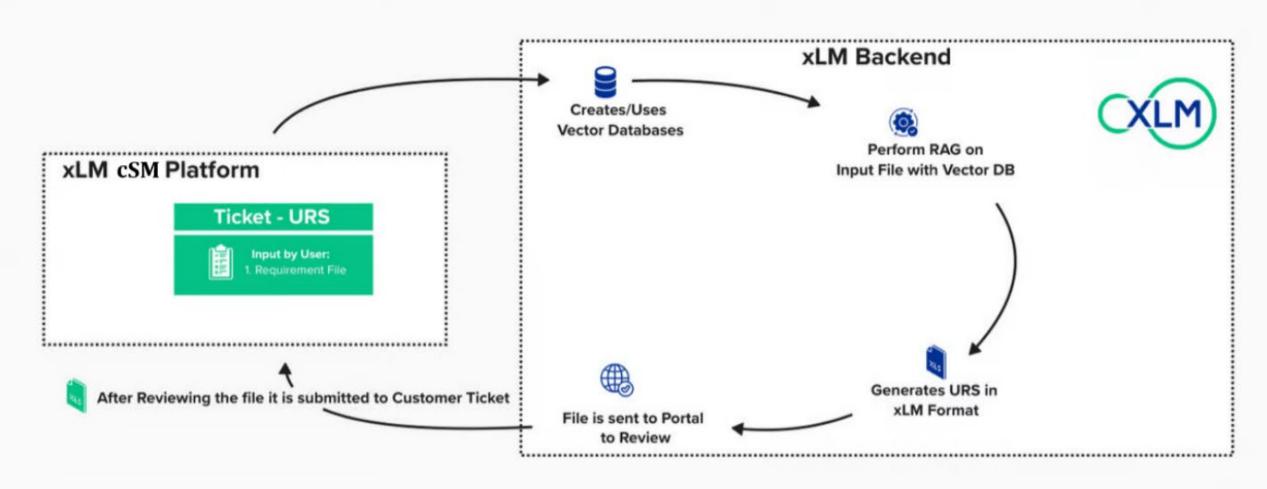
- User Requirements
 Specification (URS)
 Generation Agent
- Test Case Generation Agent
- Test Automation Agent





URS Al Agent

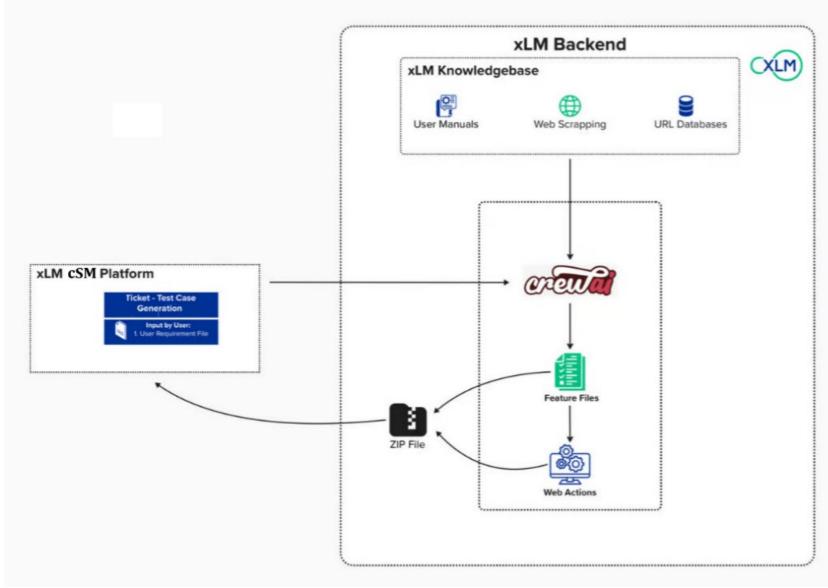






Test Case Generation Agent

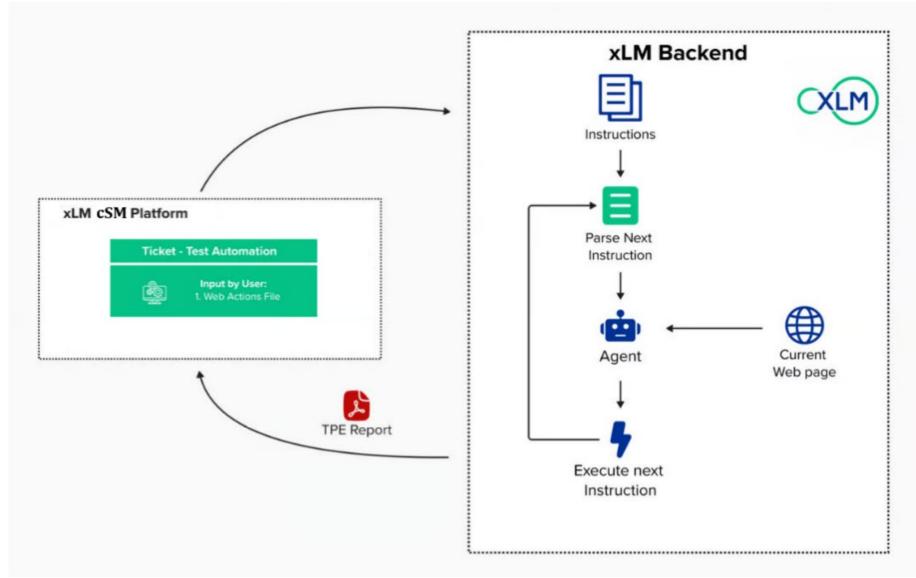






Test Execution Agent







CONNECT Proof of Concept Demo with cIV

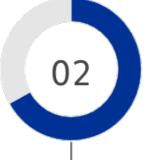






Trend Validation

Using cIV, we are going to **validate the trend data visualization** in the Aveva CDS platform.



New Dashboard Creation

Using cIV, to create a new visualization dashboard in the Aveva CDS platform.



Validation of Data Ingestion

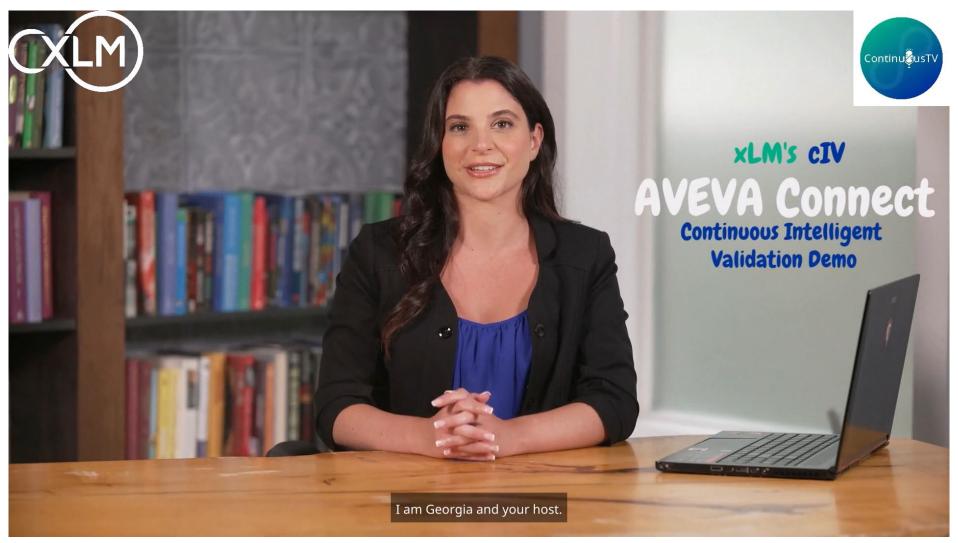
Using cIV, in the current stream available on CONNECT platform, an event will be inserted, and same event will be verified using Trend Visualization feature on CONNECT.





cIV Demo





CONNECT

Wrap-up

Future CONNECT audit trail and continuous validation



Enable Life Sciences / Pharma customers to leverage CONNECT for GxP applications







ting

Automated Test Docs



Audit Trail



Continuous Validation

Features

- 21 CFR Part 11 / Annex 11 compliance
- Continuous validation approach with 100% automated regression testing for CONNECT.
- Customer access to historical platform versioning, release notes, and qualification documentation.

Benefits

- CONNECT is always up to date with the latest features & fixes & security patches.
- Reduced compliance risks 100% regression testing.
- Compressed validation timelines while increasing quality.
- Improved compliance even while system has frequent changes.
- Increased data integrity through modern software testing.

Looking for pharma customer engagement & feedback on proposed validation approach for cloud multi-tenant SaaS!



The pharma journey with CONNECT

Today

2H25 / 1Q26

2026+

Leverage CONNECT for non GxP use cases

Enhanced data services coming (entity store +)

Digital twin bringing engineering & operations data together

Audit trail & continuous validation (data services to start)



We need your feedback!

- Please review slides with your quality / computer validation experts and gather feedback.
- Please contact Todd Brown and Tom McCarthy with a summary of your feedback and questions.
 - todd.brown@aveva.com
 - thomas.mccarthy@aveva.com
- Looking for a few engaged customers to collaborate with deeply on this topic!







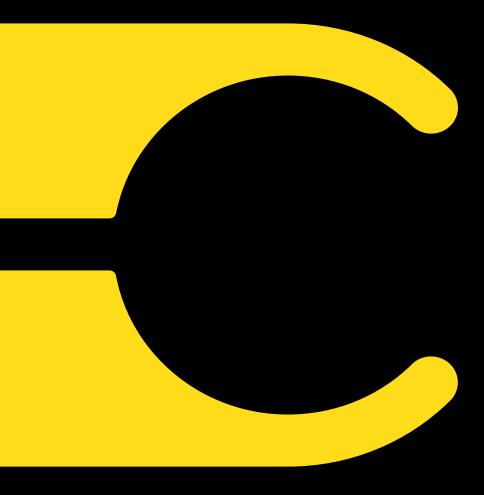
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