

Industry Use case examples of AI in the life cycle of Veterinary Medicines

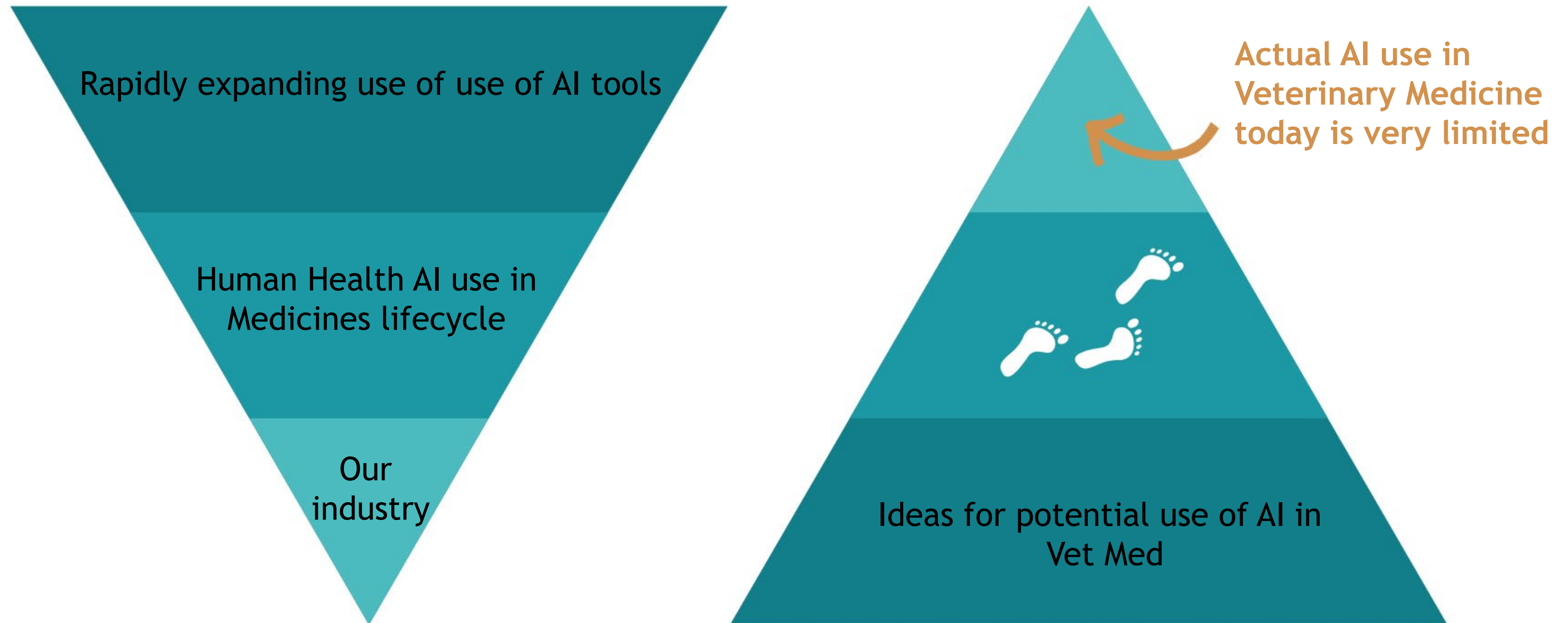
4th EMA Veterinary Big Data Stakeholder Forum

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The Veterinary Industry is in the very early stages of exploring the potential of AI



Important to keep in mind

Key Differences: Automation vs. Generative AI

Feature	Automation	Generative AI
Task Type	Repetitive, predefined	Creative, dynamic
Rules	Follows strict rules, deterministic	Learns patterns, probabilistic
Adaptability	Limited, task-specific	High, can generalize and adapt
Purpose	Efficiency in routine tasks	Creating new and unique content
Examples	Robotic Process Automation (RPA) compiling documents	Examples: GPT models, to create summaries



AI use cases in Medicines discovery and lifecycle

There is huge potential for the use AI tools in both data analytics and discover science in the Veterinary sector, but it all starts with access to good quality accurate data, interoperability of data and understanding of relationships between individual data and wider clinical information

Indications Discovery:

Biomedical Data Mining

AI-powered algorithms are being used to sift through scientific literature, vast amounts of clinical trial data and other biomedical data such as electronic health records to identify existing drugs that could be repurposed for new indications.

IMPACT: Data driven insights that could speed up the process of finding new treatments for diseases

Example

AI, specifically a deep learning-based drug-target interaction model called Molecular Transformer-Drug Target Interaction, was used to identify commercially available anti-viral drugs that could act on viral proteins of SARS-CoV-2. The model identified atazanavir, remdesivir, efavirenz, ritonavir and dolutegravir (Beck BR et al., 2020 in Computational and Structural Biotechnology Journal)

Genomic Analyses

AI is used to analyze genomic data to discover genetic markers associated with specific diseases. This work may help identify diseases that have similar markers.

IMPACT: Data-driven insights that could identify additional indications for current treatments

Predictive Modeling

Machine learning models predict which patients are most likely to benefit from a particular treatment based on their medical history and genetic profile

IMPACT: Treatments tailored to the right patient

Challenges for use in Veterinary Medicine:

Biomedical Data Mining

Limited public databases that can be used, no common repository of clinical trial data

IMPACT: We can't do this effectively yet

Genomic Analyses

Limited data sources although these are improving. Not all public access which limits potential

IMPACT: Starting to be used in early stages of discovery work dependent on data access

Predictive Modeling

These rely on data so the more available data the better these can perform, so like the other two aspects they rely on data availability

IMPACT: At the theory stage and early testing of models

Context

These examples show the potential power of AI and data analytics in indications discovery but also the challenges we have in the Veterinary sector in following the success of these approaches in Human Health

AI use cases in preparation of regulatory submissions

Industry is exploring way to make both report writing and dossier preparation more Efficient

- Giving colleagues a head start



Human-in-the-Loop (HITL) and Generative AI in the Veterinary Medical Product Development Process



Improved Efficiency with Accuracy and Reliability:

- Integrating human expertise in the process helps ensure greater accuracy and reliability. While AI algorithms can analyze medical data efficiently, humans provide context and interpret subtle nuances that may be challenging for machines alone.

Enhanced Decision-Making:

- Human-in-the-Loop systems empower Animal Health professionals to make more informed and nuanced decisions by validate AI-generated summaries and conclusions, correct errors, and provide additional insights based on their experience and expertise.

Ethical Considerations and Accountability:

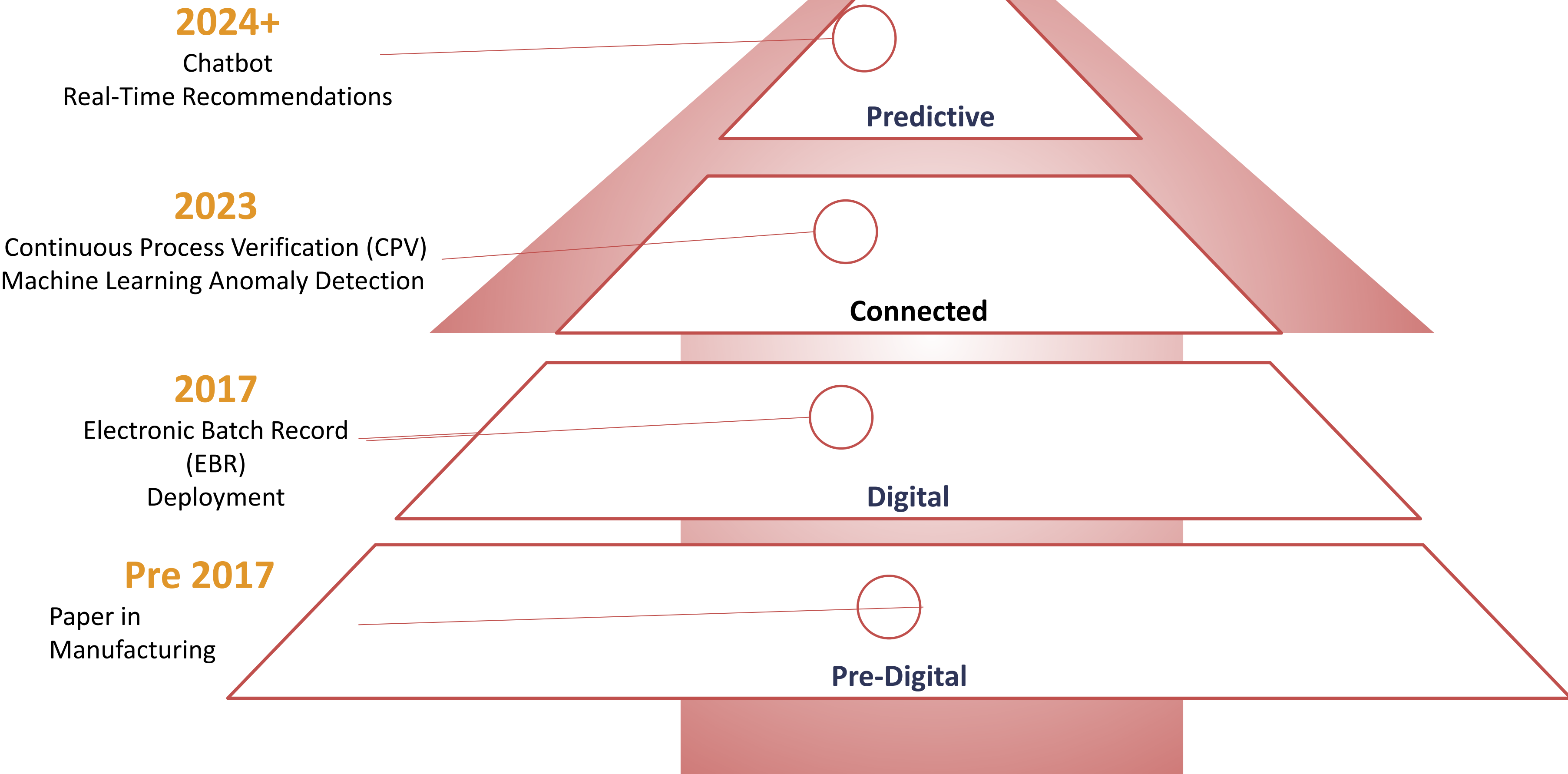
- The human presence in the decision-making loop is crucial for addressing ethical concerns. Having human oversight ensures accountability, transparency, and adherence to ethical standards.

A photograph of a white sheep with yellow ear tags standing in a field of tall grass. In the background, there is a body of water and rolling hills under a hazy sky. The image is partially obscured by a teal and orange vertical bar on the left side.

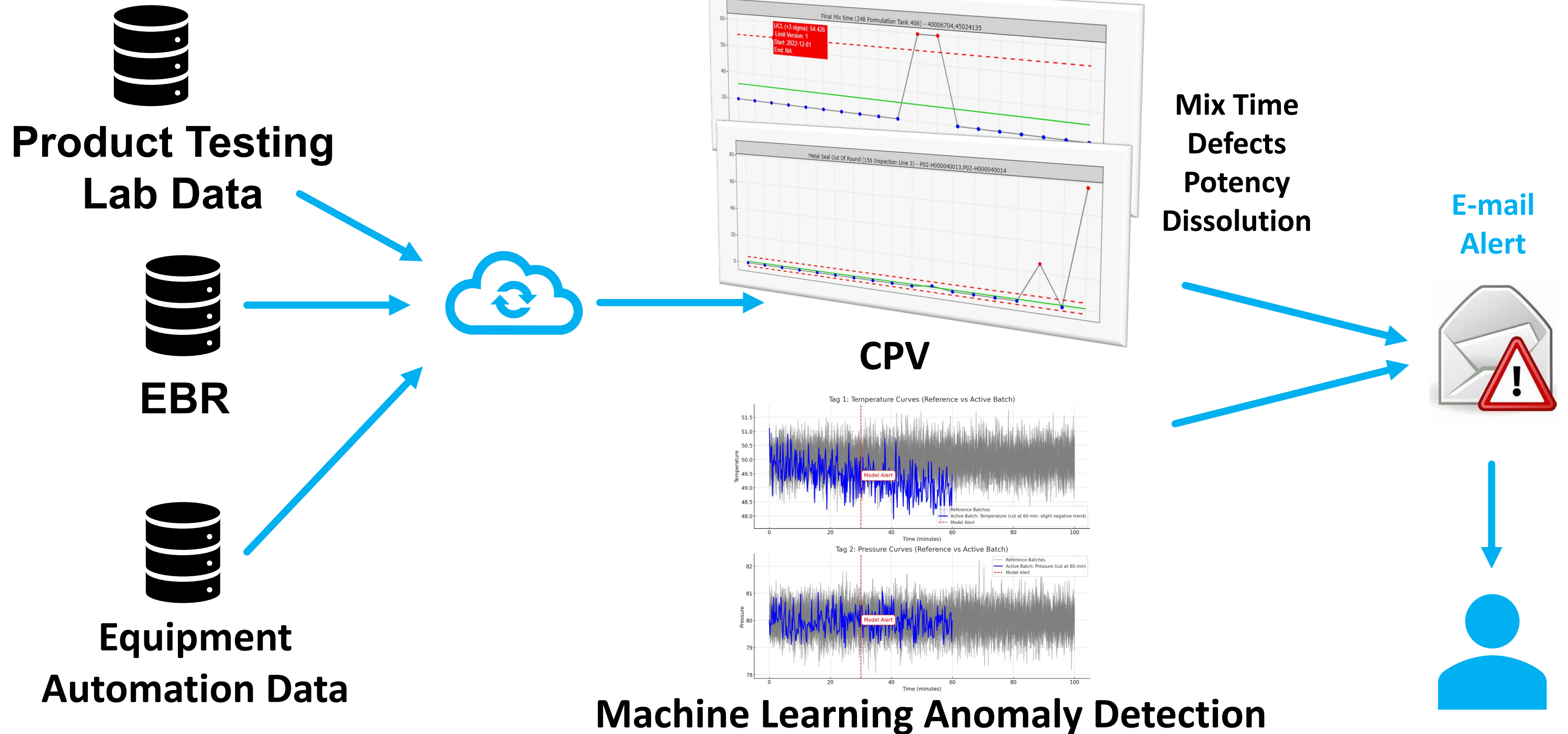
AI use cases in GMP Manufacturing

- AI use in manufacturing is currently focused on process monitoring and improvement
- Has the potential to more quickly identify both issues and process improvements
- Industry is slowly starting to explore potential, and this will only increase
- Need awareness with GMP inspectors of these types of approaches and appropriate guidance in acceptance/expectations/validation of us in a GMP context – link to GMP guidance revision

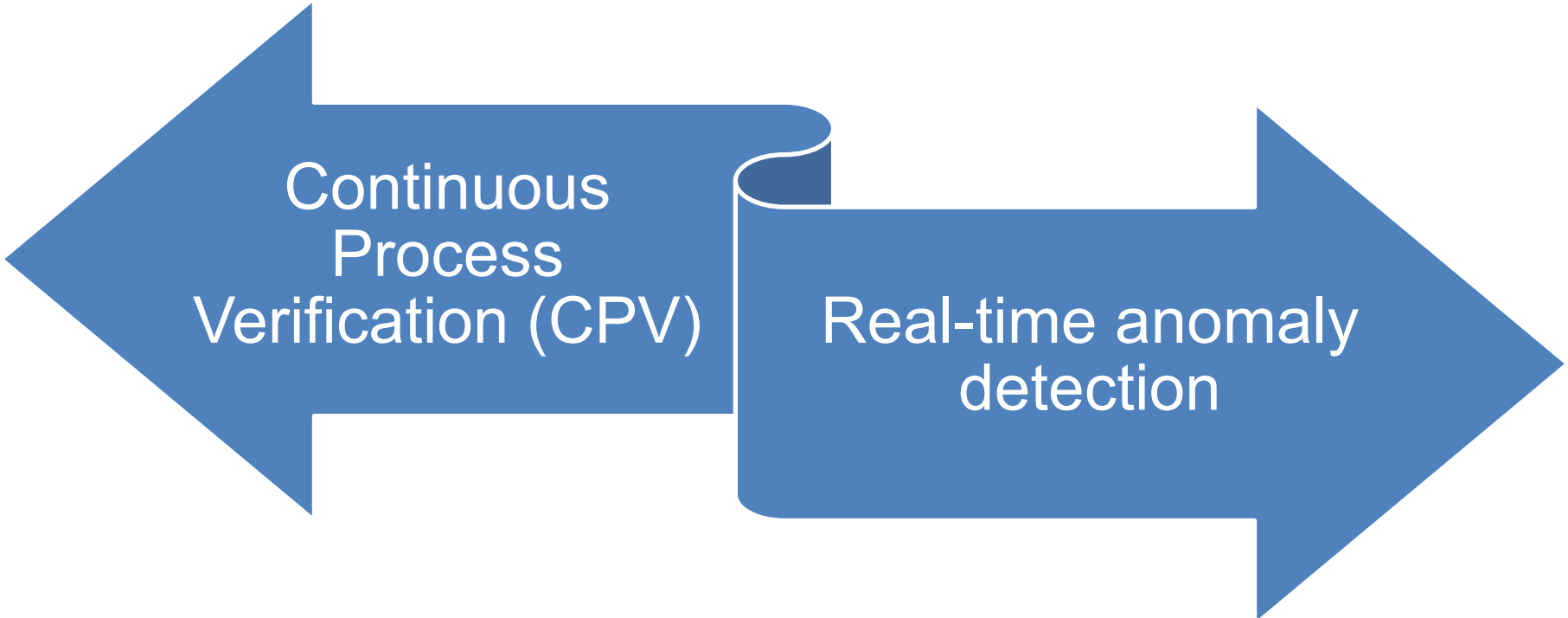
Future Manufacturing Digital Journey



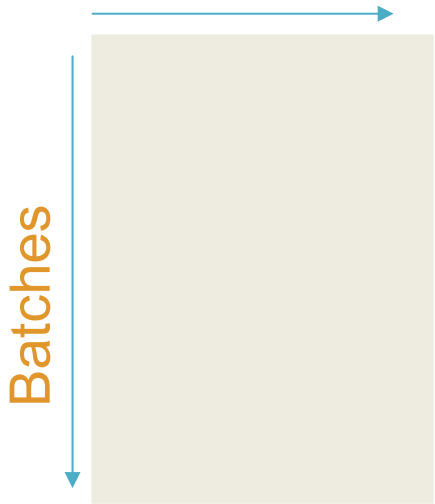
Continuous Process Verification (CPV) & Machine Learning (ML) Models



CPV vs. Machine Learning Models

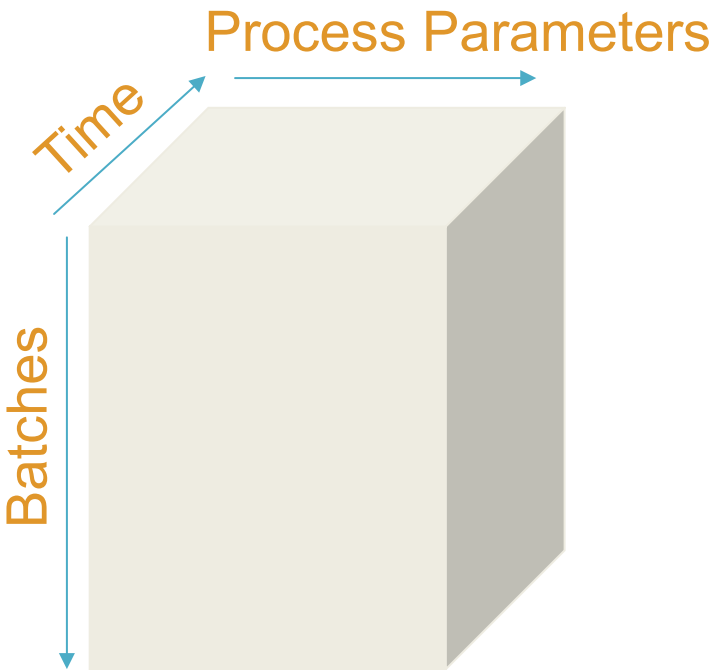


Critical Process Parameter
Critical Quality Attribute

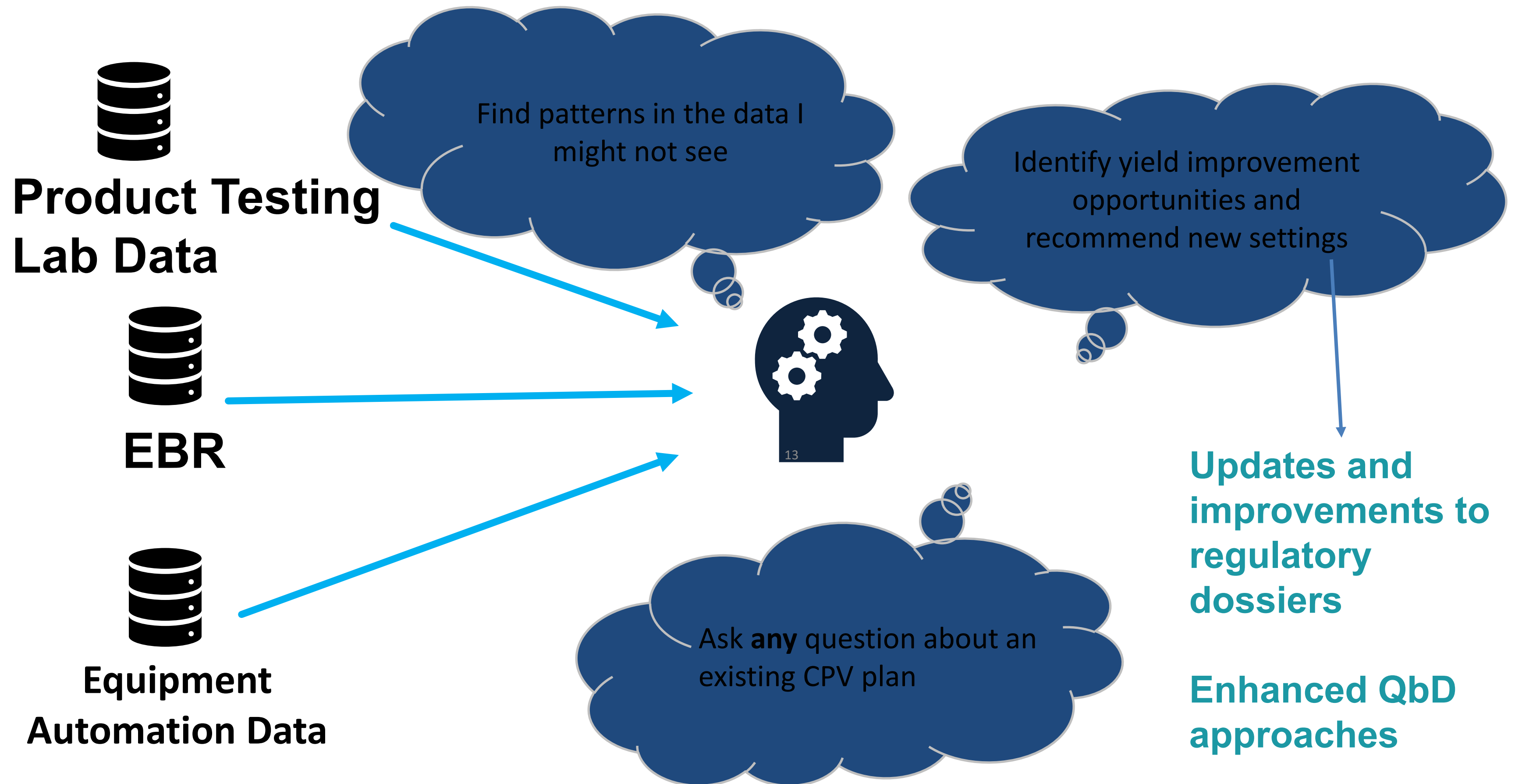


How do batches look **over time**?
After-the-fact hindsight
Observation = batch
Often univariate

How is the **current batch** performing?
Real-time insight
Observation = batch-time
Multivariate



AI for Manufacturing – “Help me to...”





AI uses in Pharmacovigilance

AI tools are starting to be used in Human Health Pharmacovigilance

- Current Human Health use cases focus on transitioning a PV form to a PV case but this but in AH typically this is not the model where individuals enter cases directly (no interim form)
- We need to tread carefully and in consultation with Regulatory agencies as we explore potential PV use cases
- Still expectation of individual case review by a real person

Starting point – data

A long journey

Data analytics is our first step and data visualisation - this will then lead on to uses of AI to understand and interpret the data and make inferences or reach conclusions

Currently too much data is un-structured to fully utilise AI tools and there are differences in both case quality and case completeness that impact use

Areas of future interest:

- Case processing

- Case assessment

- Signal management (beyond statistical measures eg PRR)

- LLM and unstructured narrative data

This could include natural language processing (NLP) to collect case data, machine learning (ML) to apply clinical sign codes to cases, causality assessment based on predefined criteria.

The potential outcome is higher quality data with a higher rate of consistency of data which in turn impact the quality of signal management BUT this is just theory – we are a long way from here.

Use cases for Signal Management

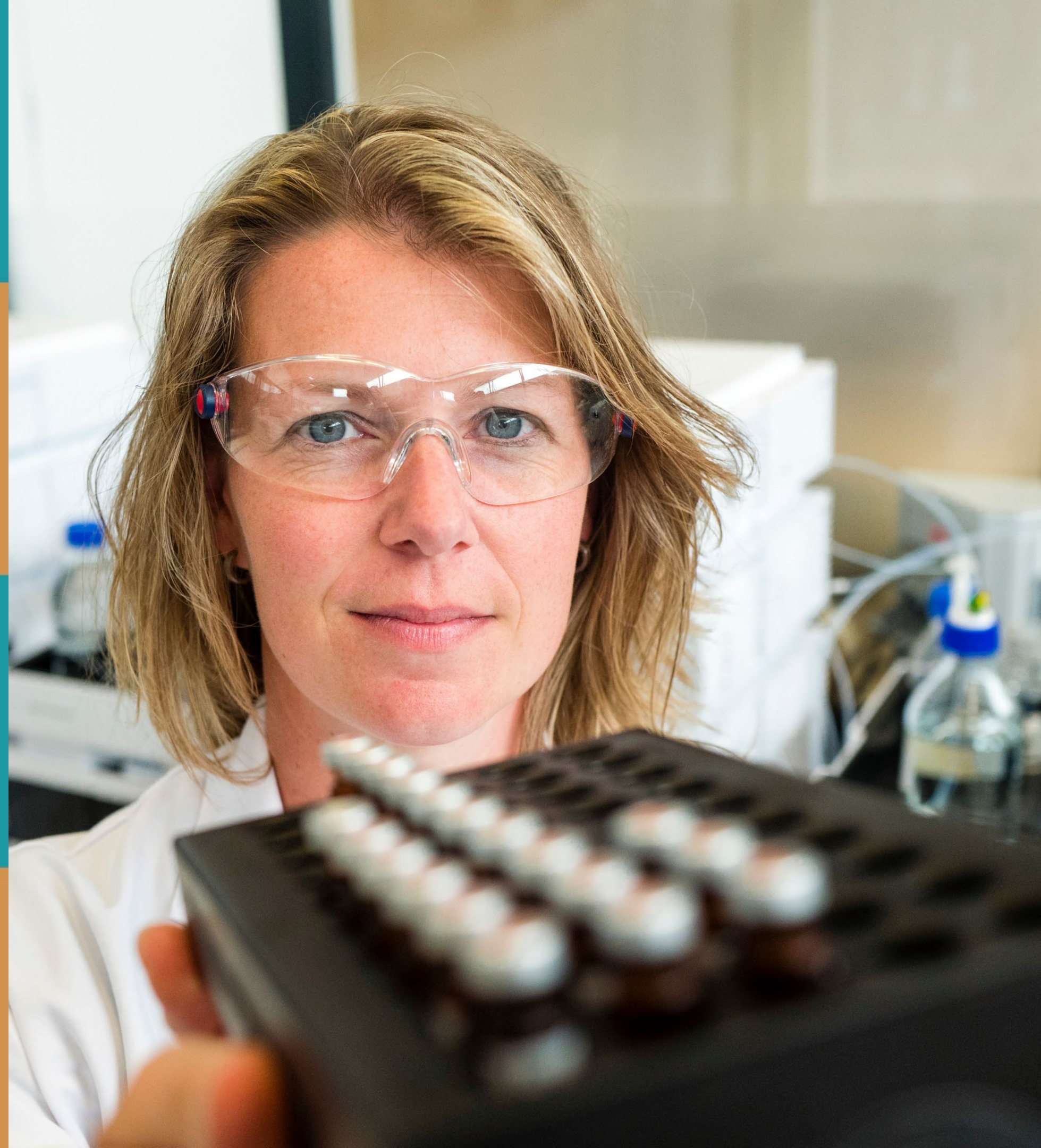
PV Signal Management is an area that has a lot of opportunity for AI:

- Data analytics and summarization
- Pattern detection
- Predictive modeling simulate and predict which individuals may experience an adverse event

Also investigating options to use AI to summarize multiple adverse event narratives, apply medically derived logic to categorize cases, identify trends and commonalities among cases, and develop new methodologies for more effective signal detections (i.e., reduce our false positive rate).

All of this is possible but will require close collaboration with regulators and PV inspectors as we move in this direction to ensure understanding of the process and confidence in both the data and outcomes/inferences

Not AI yet but currently using robotic process automation (RPA) to perform signal detection runs and apply business logic to results to identify potential signals.



Conclusions

There is huge potential for the use of AI across the Veterinary Medicines Lifecycle

Focus of interest for industry is to get better and faster insights into our data whether that is to support discovery and innovation, manufacturing or post approval surveillance

Exploring AI tools that make our processes more efficient and allow colleagues to do more better

AI tools in Veterinary medicines can enhance our ability to deliver high quality safety and efficacious products to support Animal Health and Welfare, respond to health emergencies and support One Health.

The AI journey is just beginning.....

Thank you!



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