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EXPLORING DATA
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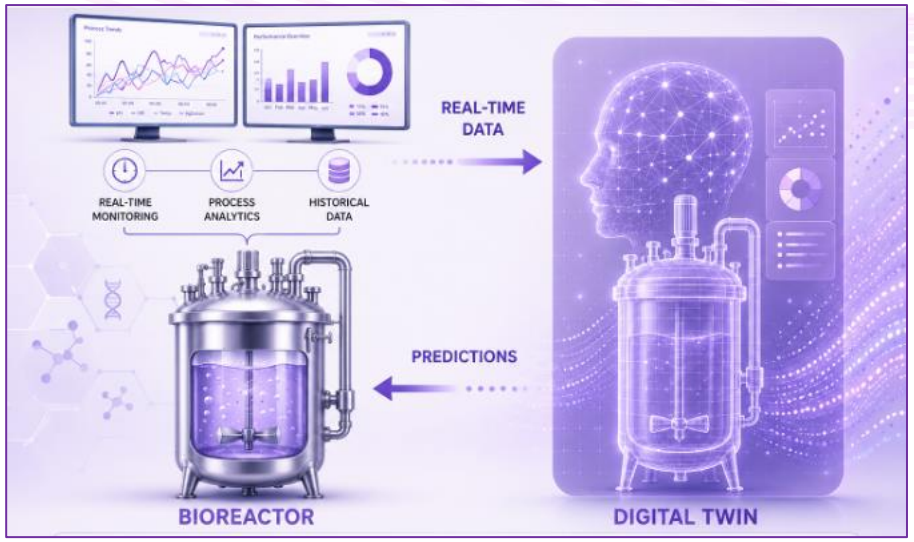

Democratising AI for Pharmaceutical Process Optimisation using JMP

Anurag Seksaria

(2026-US-30MP-2984)

PROCESS OPTIMIZATION | IMPROVED PRODUCT QUALITY | REDUCED RISK | HIGHER EFFICIENCY

Objective

1. Optimisation of Yield for a Complex Pharma Process
2. Provide an approach which can be Democratised

Key Challenges

- Process parameters are manged ***"Real Time"*** while Yield is known only at the **"End of Fermentation"**
- High variability in Raw Material Quality difficult to assess

U-OSEMN Model

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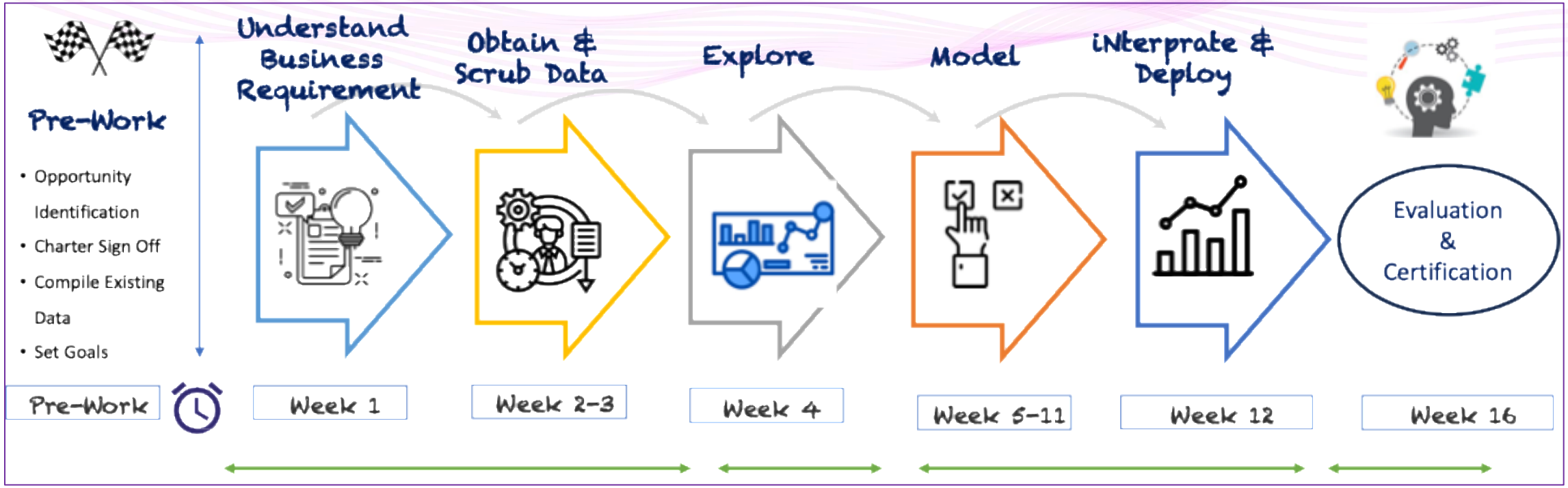

"A Taxonomy of Data Science" Hilary Mason and Chris Wiggins,

Controlled Microbial Fermentation Process

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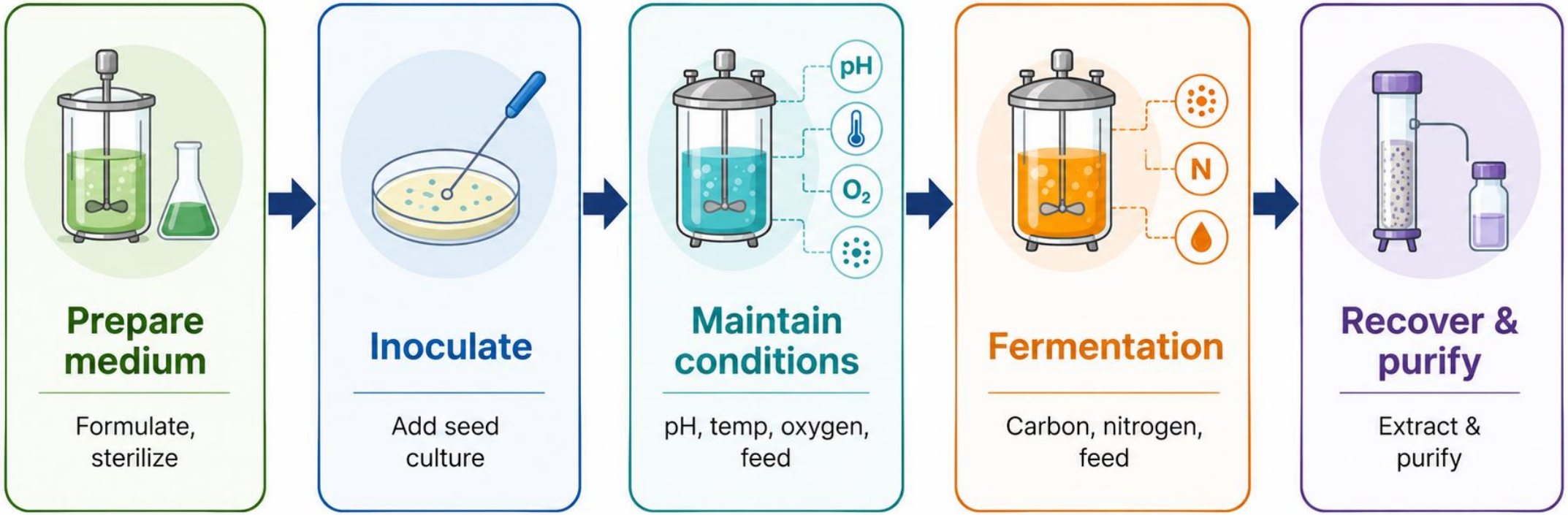

Influencing Factors

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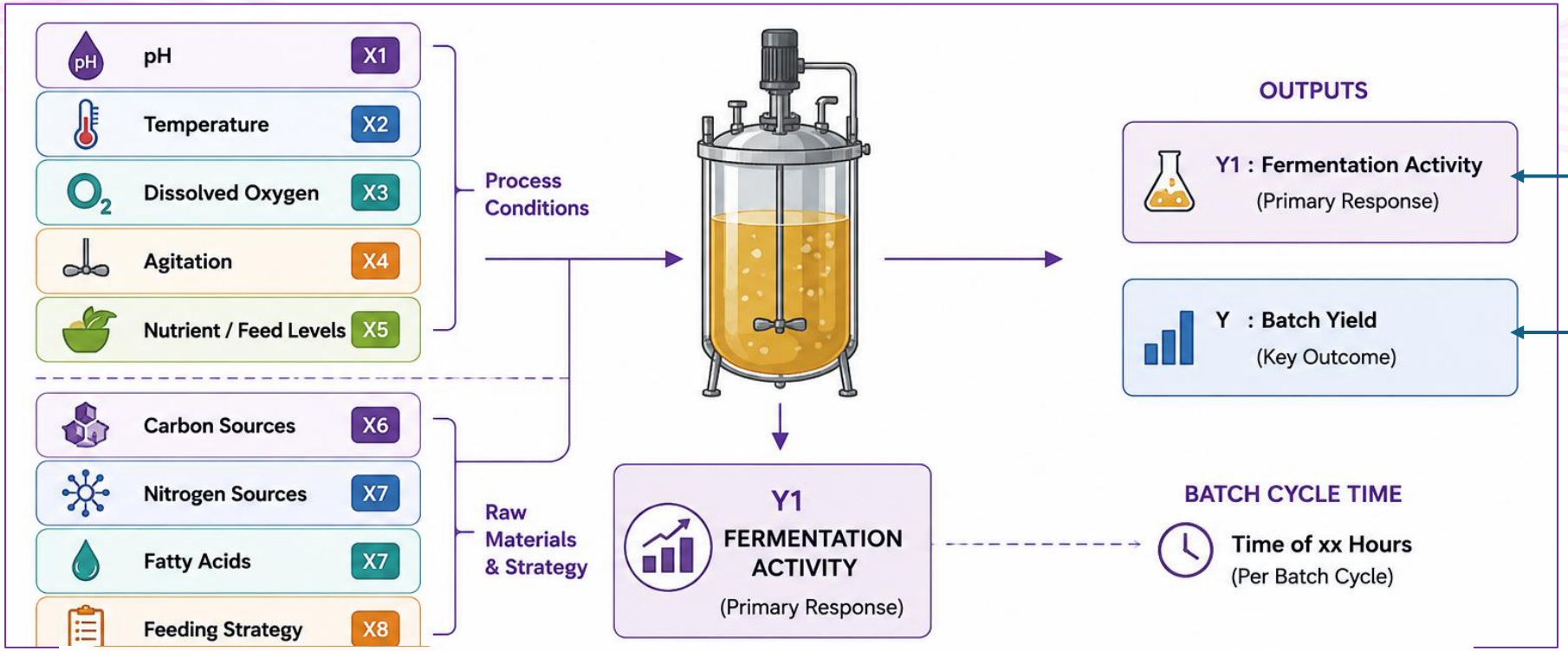

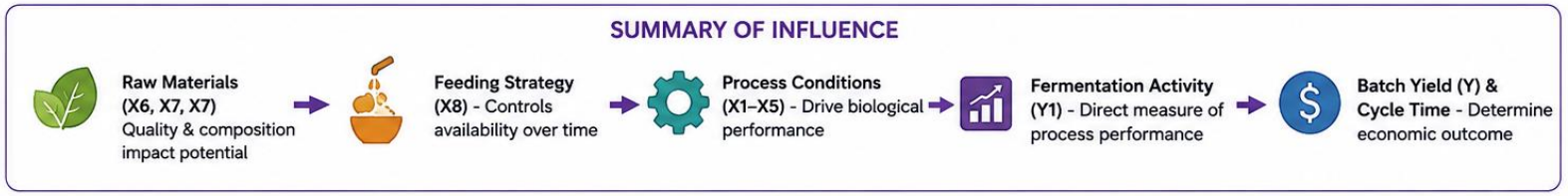

Interrelationship Between Factors

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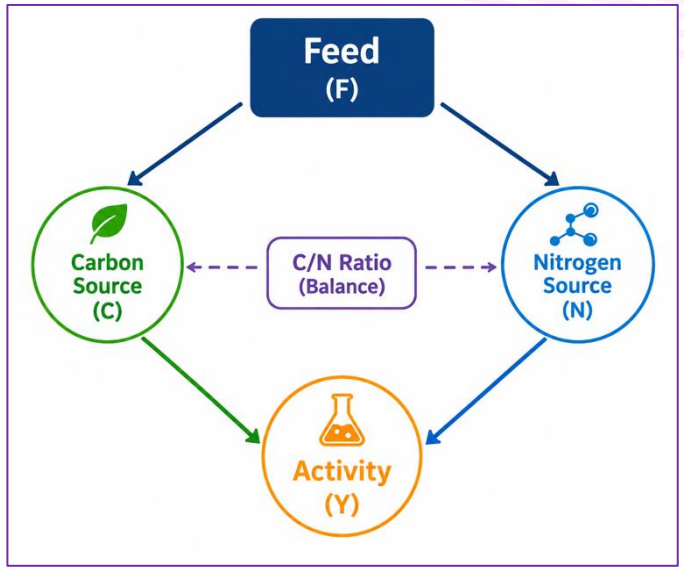
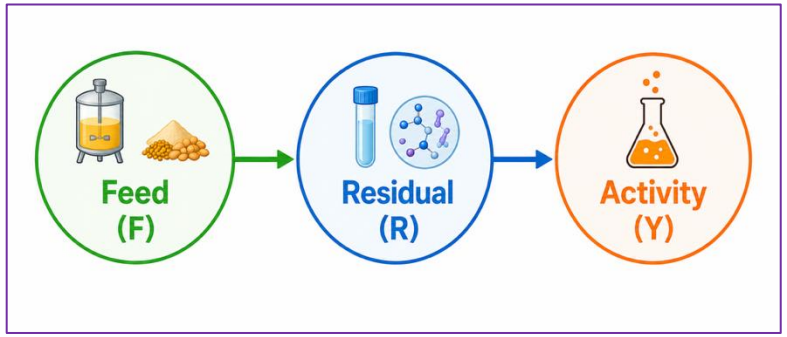
Confounding



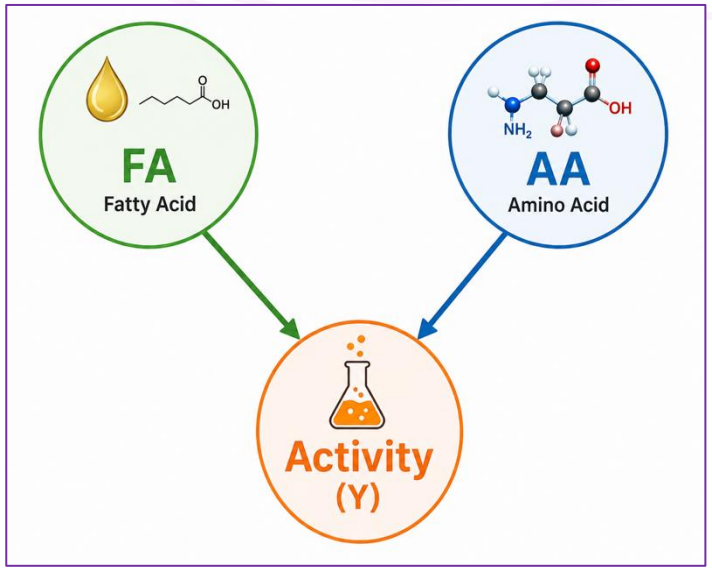
Feed -> Carbon & Nitrogen Carbon/ Nitrogen Ratio

Sequential



Feed v/s Residual

Converging



Fatty & Amino Acids independently impact Activity

Log Hours v/s Fermentation Activity (Y1)

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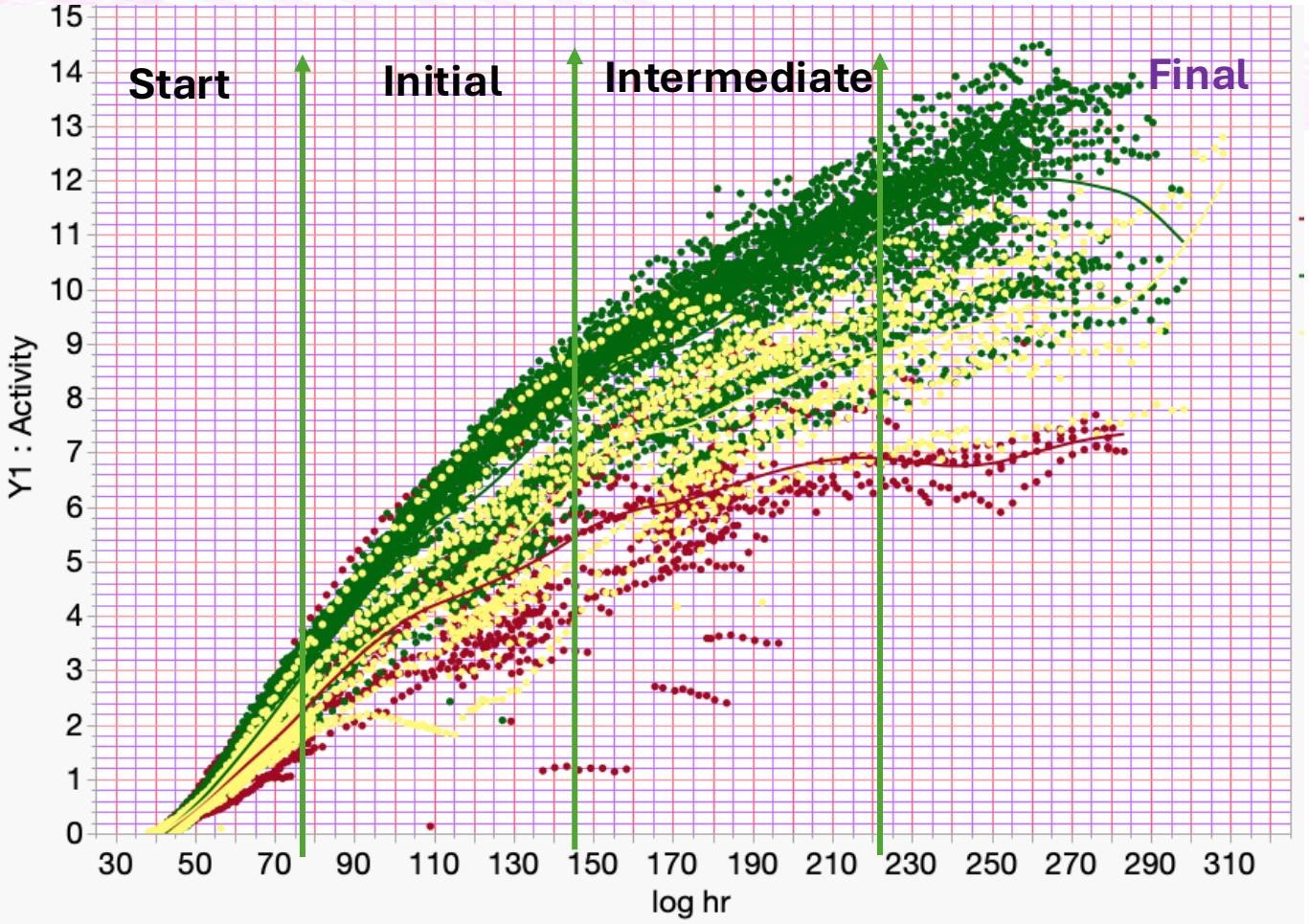

Green : High Yield
Yello : Medium Yield
Red : Low Yield

For better analysis, the process was **SPLIT** into **4 STAGES** using "***Rate of Change"***

- Start
- Initial
- Intermediate
- Final

Bases for Creating SPLIT

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Stage Start/High Yield

Summary of Fit

RSquare	0.834279
RSquare Adj	0.834141
Root Mean Square Error	1.064479
Mean of Response	3.897046
Observations (or Sum Wgts)	1206

Parameter Estimates

Term	Estimate	Std Error	t Ratio	Prob>|t|	Lower 95%	Upper 95%
Intercept	-0.660512	0.066079	-10.00	<.0001*	-0.790155	-0.530868
log hr	0.0318449	0.000409	77.85	<.0001*	0.0310424	0.0326474

Stage Final/High Yield

Summary of Fit

RSquare	0.947313
RSquare Adj	0.947279
Root Mean Square Error	0.812768
Mean of Response	5.359206
Observations (or Sum Wgts)	1548

Parameter Estimates

Term	Estimate	Std Error	t Ratio	Prob>|t|	Lower 95%	Upper 95%
Intercept	-1.170447	0.044278	-26.43	<.0001*	-1.257299	-1.083594
log hr	0.0450844	0.00027	166.72	<.0001*	0.044554	0.0456148

Regression Analysis by Low & High Yield Batches

Stage wise Activity

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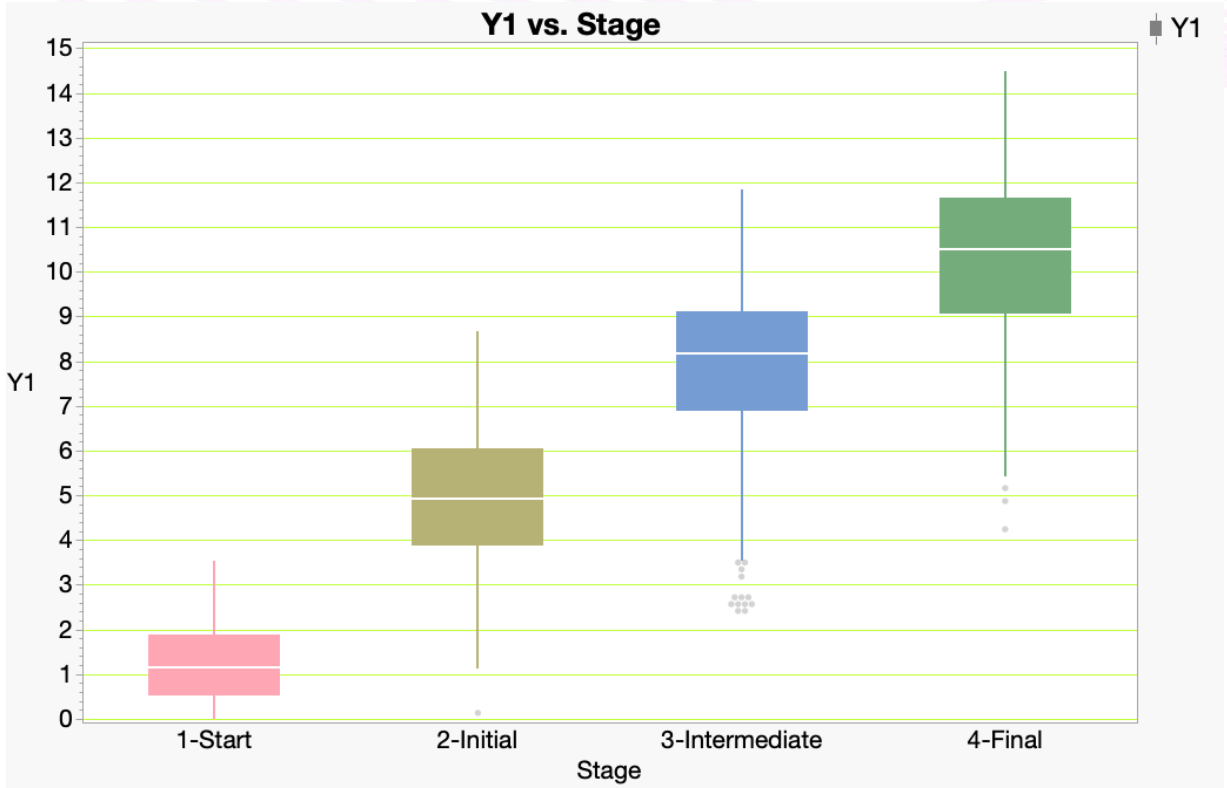

Significant difference between stages for both ***Averages*** and ***Variation*** for Activity

Exploration - Each Variable Stage Wise

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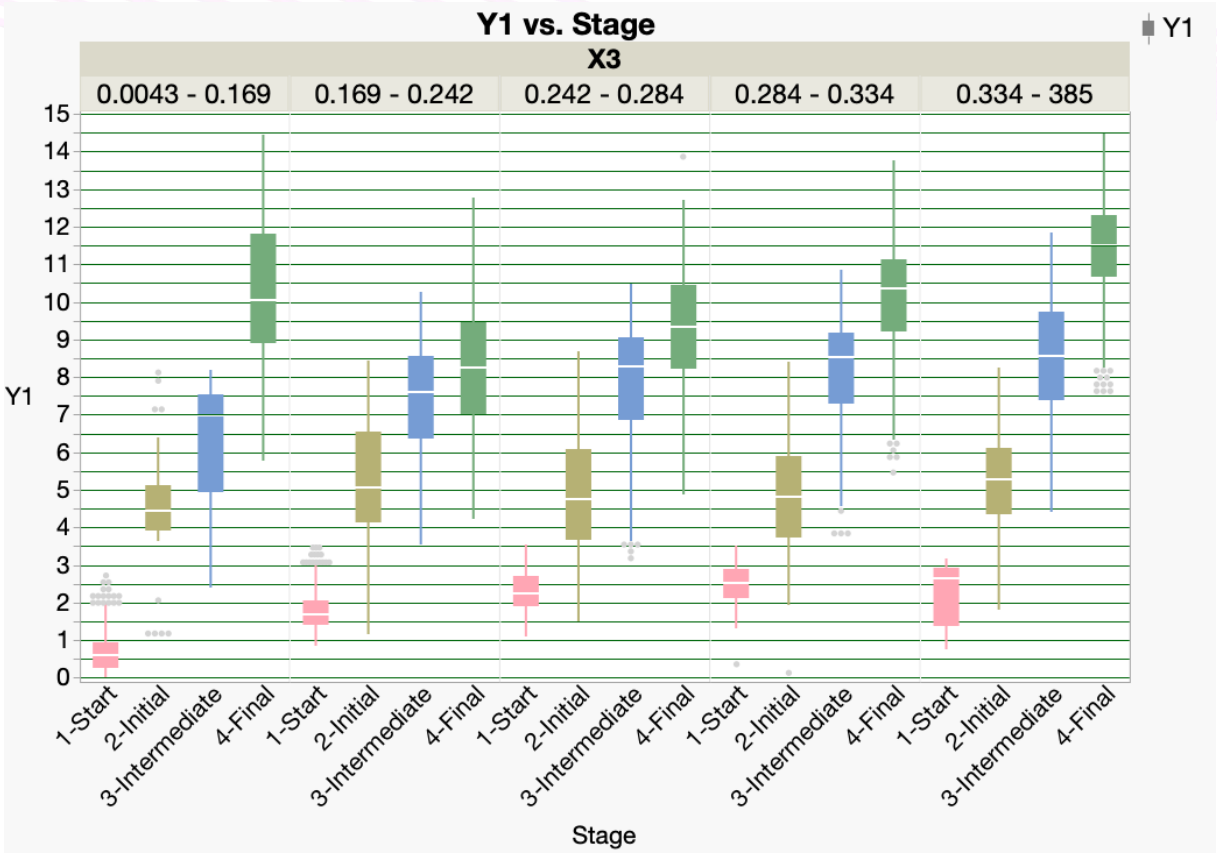

Variable X3 – The optimal levels vary with stages of fermentation

Tree – Stage Wise Optimization

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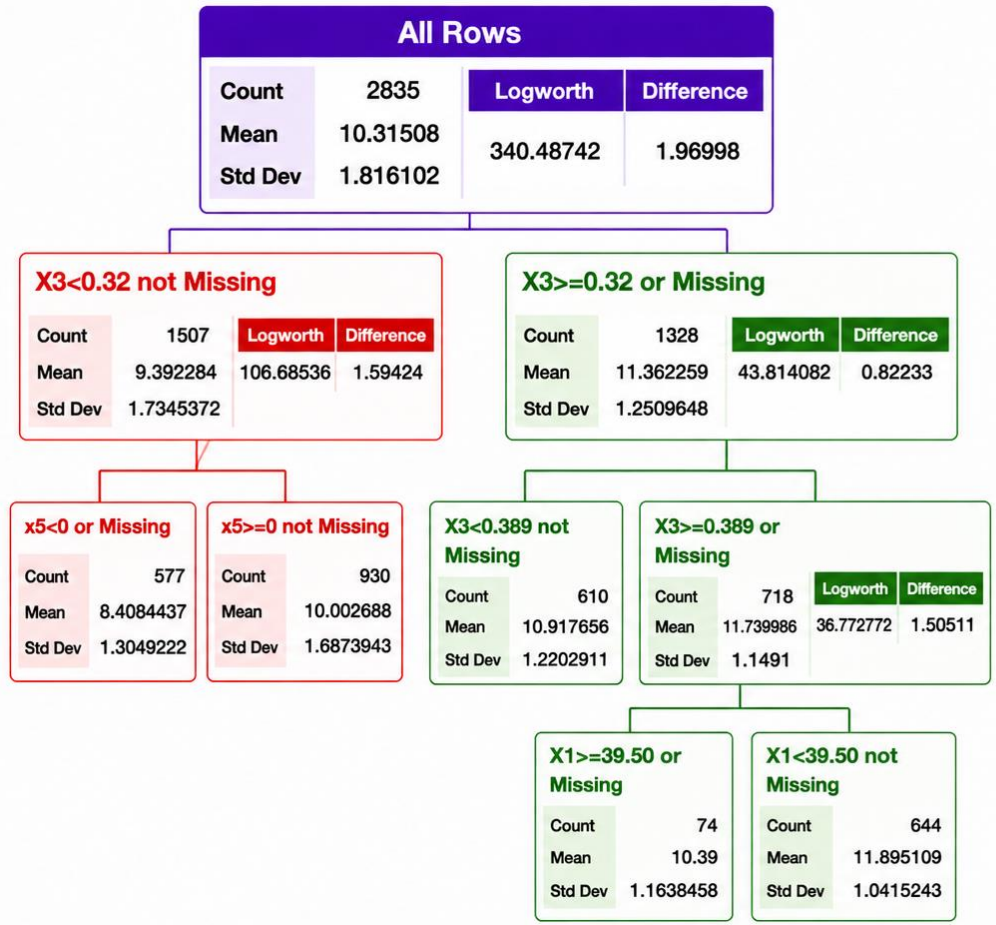

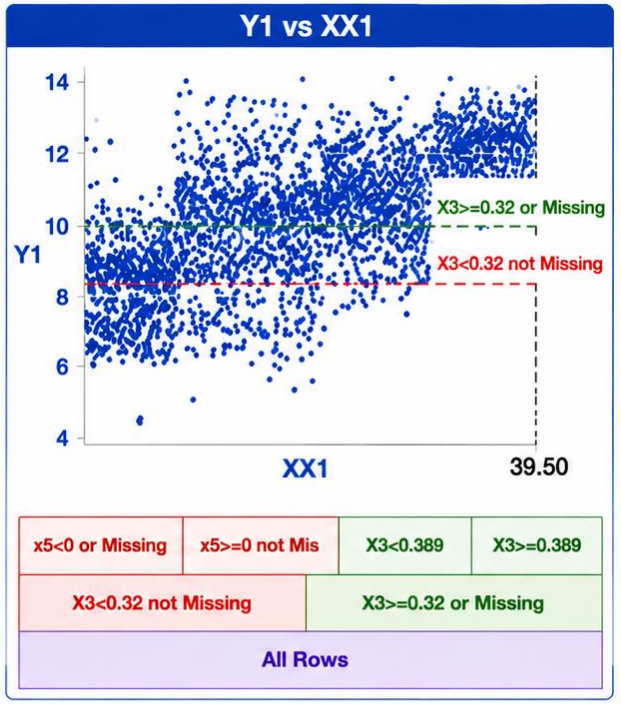

RSquare	RASE	N	Number of Splits	AICc
0.430	1.3710569	2835	4	9846.76

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Fine Tunning Optimal with Profiler

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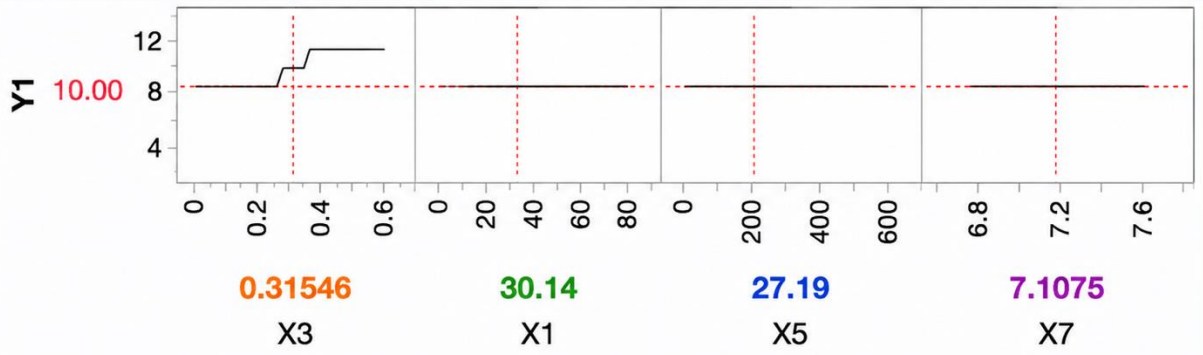
Column Contributions

Term	Number of Splits	SS	Portion
X3	2	3066286.12	0.6214
X1	6	1089294.67	0.2208
X5	3	431444.028	0.0874
X7	3	347145.47	0.0704

Prediction Profiler



Fine Tuning between recommendations through TREE Analysis & Profiler

Bayesian Approach

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SN	ANALYSIS	RELATIONSHIP / OUTPUT	PURPOSE
1	Feed Duration Effect	Response = f(Feed Hours)	Determine optimum feed duration for maximum response & efficiency.
2	Input A–Feed Relationship	Response (Y) = f{Input A (y_1), Feed Rate (x_1)}	Understand combined effect of input A & feed rate on response.
3	Input B–Feed Relationship	Response (Y) = f{Input B (y_2), Feed Rate (x_1)}	Understand combined effect of input B & feed rate on response.
4	Input A–Additive 1 Relationship	Response (Y) = f{Input A (y_1), Additive 1 (x_2)}	Assess the effect of additive 1 addition with input A on response.
5	Input Relationship (A vs B with Additive 1)	Input A (y_1) = f{Input B (y_2), Additive 1 (x_2)}	Understand interrelationship between inputs & additive 1.
6	Additive Usage Year-on-Year Comparison	Year 1 vs. Year 2 (w.r.t. Additive 1, Additive 2)	Compare performance & consumption patterns of additive 1 & additive 2.
7	Additive 1 Level Impact	Response (Y) = f(Additive 1 Level)	Identify optimum level/range of additive 1 for desired response.
8	Additive 2 Level Impact	Response (Y) = f(Additive 2 Level)	Identify optimum level/range of additive 2 for desired response.
9	Process Interaction Key Inputs & Additives)	Response (Y) = f{Input A, Input B, Additive 1,2..., Feed Rate}	Evaluate interaction effects among key inputs, additives & feed rate.
10	Process Profile Analysis Over Time	Parameter 1 & Parameter 2 vs. Log Hours	Analyse trajectories of key parameters & process stability over time.
11	Correlation & Association Analysis	Correlation among Key Inputs, Additives, Response	Identify strong associations influencing the response & detect multicollinearity.
12	EOF Analysis	EOF by Time (using calculation)	Determine End of Process (EOF) at the right time.
13	Optimization Analysis	Multi-response optimization using key inputs, additives & feed rate	Identify optimal combination of factors for maximizing response & minimizing cost.
14	Outlier & Anomaly Detection	Detection of outliers in Key Parameters & Response	Ensure data quality & reliability by identifying abnormal observations.
15	Sensitivity Analysis	Impact of ± change in inputs/additives on response	Identify critical factors & robustness of the process.
16	Contribution / Pareto Analysis	% Contribution of each factor to response variation	Focus improvement efforts on factors that contribute the most to performance.
17	Robustness & Stability Assessment	Process Performance across batches / days / conditions	Validate consistency & robustness of process under normal operating ranges.
18	Predictive Modeling (AI/ML)	Build predictive model for response using key factors	Predict future outcomes, support decision making & enable real-time process control.

Results & Deployment

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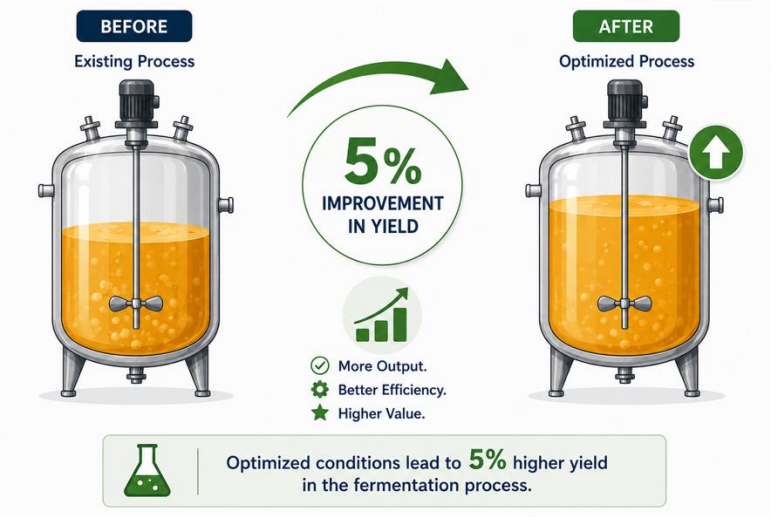

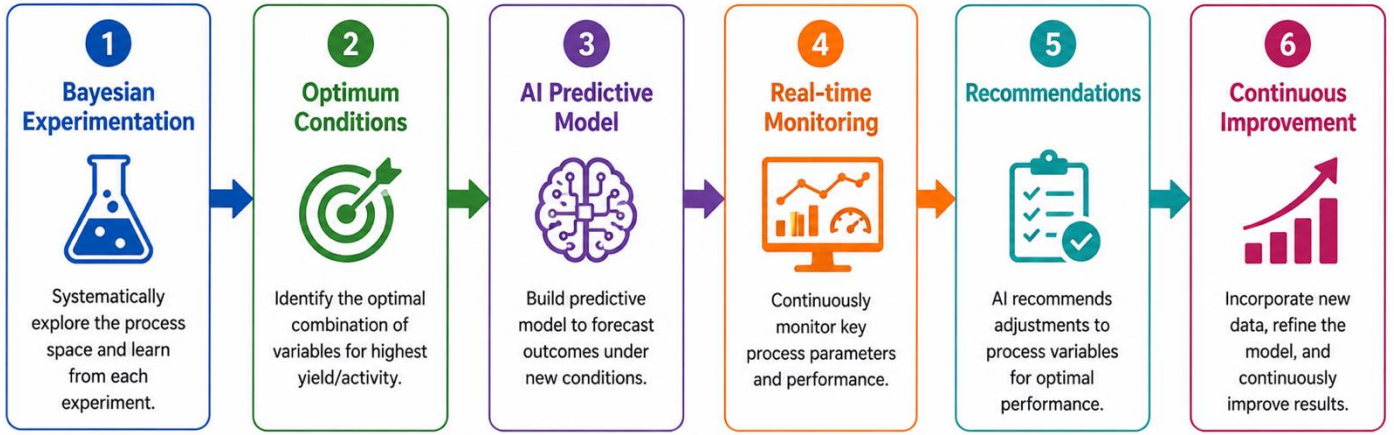

Digital Twin Helps Operations Team to Run Process Optimally


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