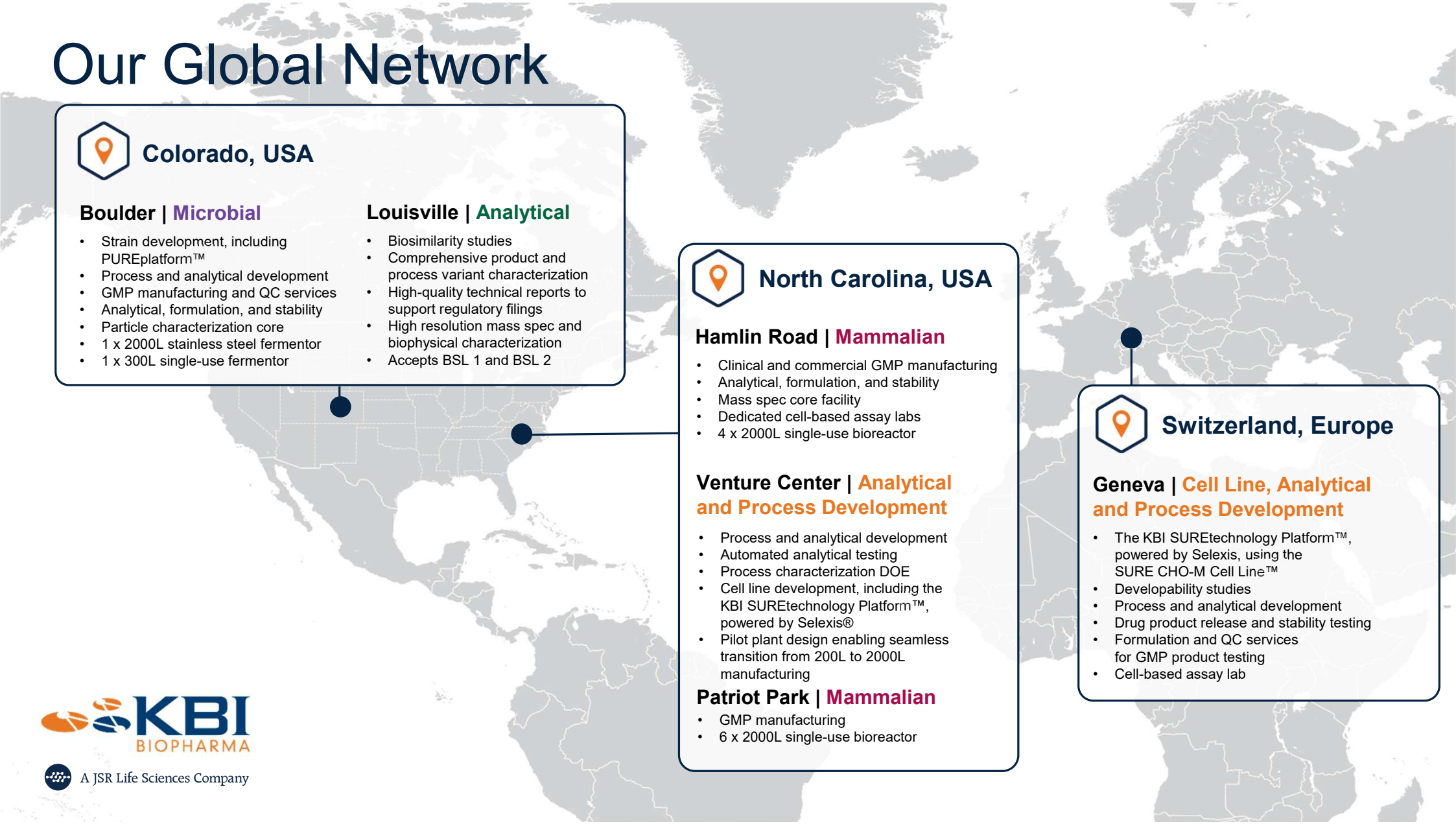
A JSR Life Sciences Company

KBI BIOPHARMA

Leveraging Bioprocess Development: Transforming Data into Business Success

Alix Lecomte – 26 June 2025

Our Global Network



Colorado, USA

Boulder | Microbial

- Strain development, including PUREplatform™
- Process and analytical development
- GMP manufacturing and QC services
- Analytical, formulation, and stability
- Particle characterization core
- 1 x 2000L stainless steel fermentor
- 1 x 300L single-use fermentor

Louisville | Analytical

- Biosimilarity studies
- Comprehensive product and process variant characterization
- High-quality technical reports to support regulatory filings
- High resolution mass spec and biophysical characterization
- Accepts BSL 1 and BSL 2

North Carolina, USA

Hamlin Road | Mammalian

- Clinical and commercial GMP manufacturing
- Analytical, formulation, and stability
- Mass spec core facility
- Dedicated cell-based assay labs
- 4 x 2000L single-use bioreactor

Venture Center | Analytical and Process Development

- Process and analytical development
- Automated analytical testing
- Process characterization DOE
- Cell line development, including the KBI SUREtechnology Platform™, powered by Selexis®
- Pilot plant design enabling seamless transition from 200L to 2000L manufacturing

Patriot Park | Mammalian

- GMP manufacturing
- 6 x 2000L single-use bioreactor

Switzerland, Europe

Geneva | Cell Line, Analytical and Process Development

- The KBI SUREtechnology Platform™, powered by Selexis, using the SURE CHO-M Cell Line™
- Developability studies
- Process and analytical development
- Drug product release and stability testing
- Formulation and QC services for GMP product testing
- Cell-based assay lab

KBI BIOPHARMA

A JSR Life Sciences Company

CDMO environment in a nutshell

Innovation

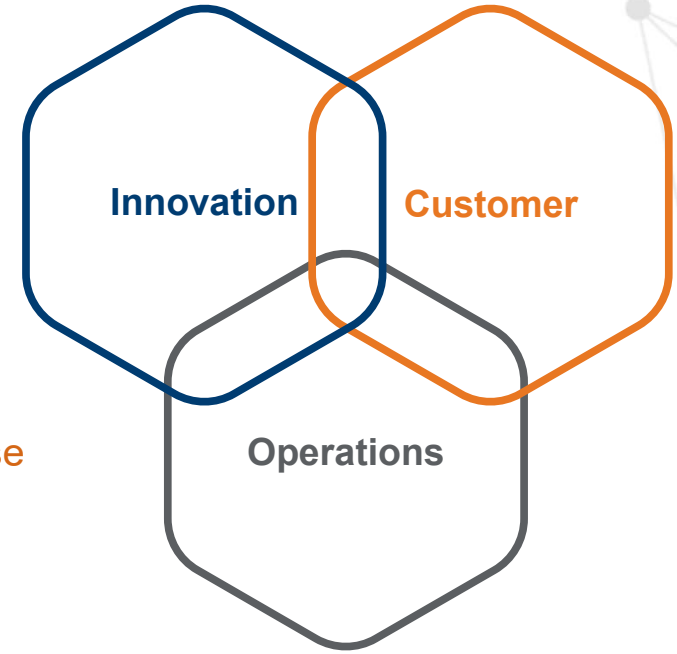
- High Productivity
- Short Timelines
- Pricing

Customer

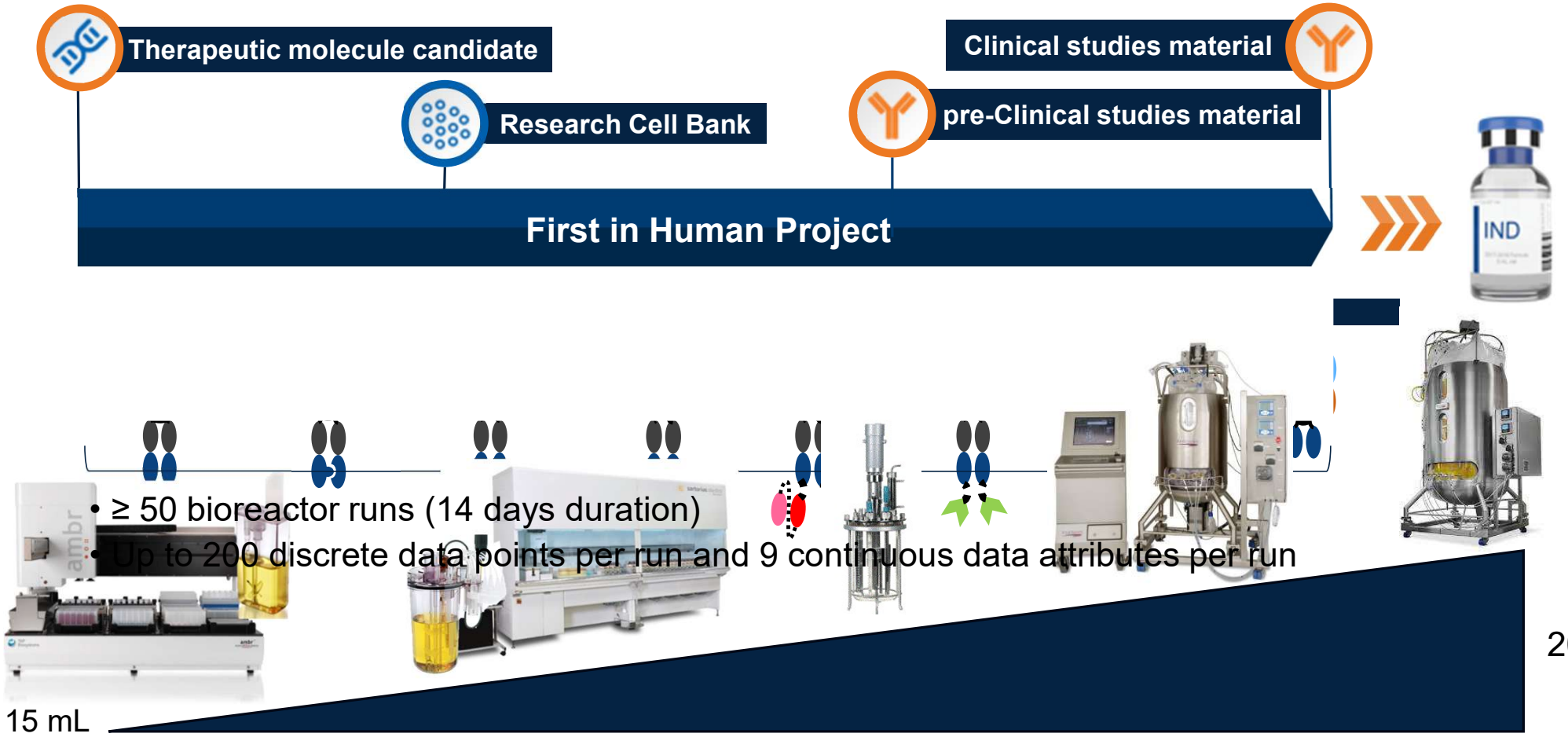
- High Scientific Expertise
- Flexibility
- Transparency/Trust
- Confidentiality

Operations

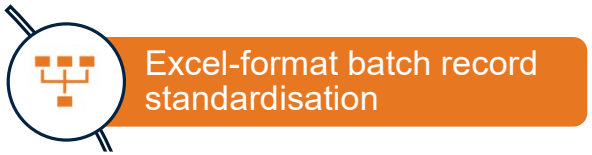
- Technical competence
- Efficient Tools in place for lab execution and data analysis tasks



Typical KBI Platform Workflow



Process Data Standardization Journey

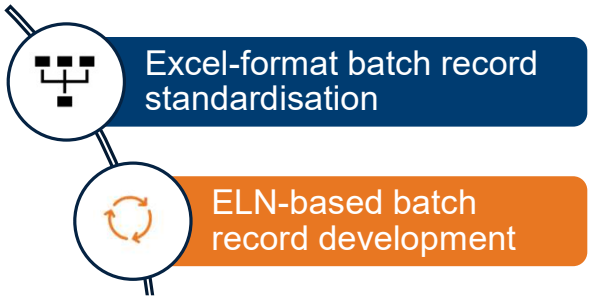


Where we started:

- Non Harmonized Excel-based batch records
- No database tools in place to compare projects side by side

Initial Objective: Standardize across sites and teams data recording in Excel-Format

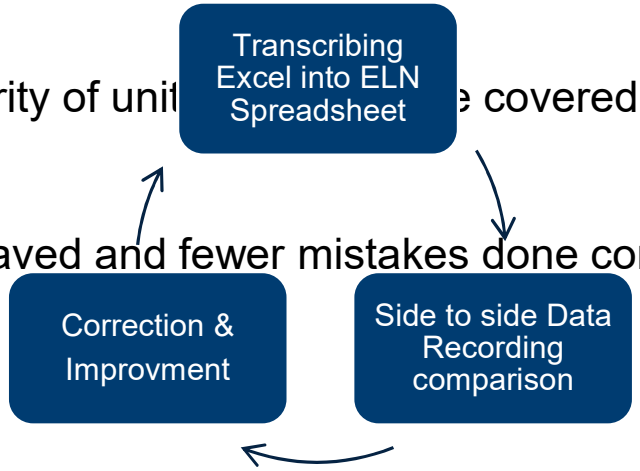
Process Data Standardization Journey



Objectives: Transform data recording to a multidimentional format

Steps:

- Iterative process for each unit operation
- A majority of unit[illegible]e covered and available
- Time saved and fewer mistakes done compared to the Excel-based format



Process Data Standardization Journey

- Excel-format batch record standardisation
- ELN-based batch record development

Template Configuration

		Value
Number of Conditions		1
Conditions	Condition 1	Main
Number of Passages		3
Number of Flasks per Passage	Passage 1	1
	Passage 2	2
	Passage 3	2
Number of Supplement Solution		0
Flask Size Varies within the Passage?		Yes
Flask Media Varies Within the Passage?		Yes
Flask Supplements Vary Within the Passage?		No
Pre-Warm Parameters Vary Within the Passage?		No
Incubation Parameters Vary Within the Passage?		No

ent Execution

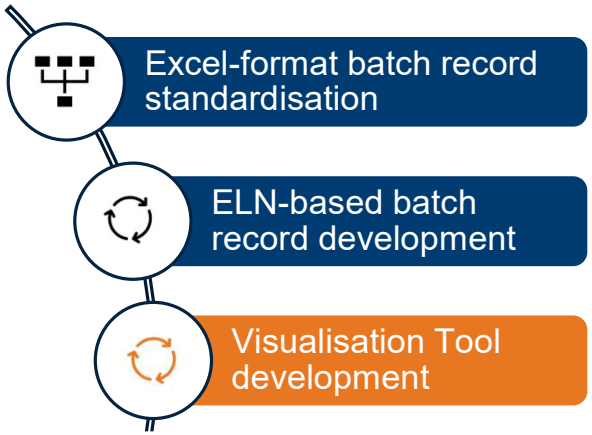
Number of conditions, steps

Sampling for Passage?	Sample Date / Time		Extra Row Required?	Viable Cell Density (x 10^6 cells/mL)	Total Cell Density (x 10^6 cells/mL)	Viability(%)
	Date	Time				
	13Feb2024	17:03	X	0.3	0.3	100
Yes	16Feb2024	10:00		4.5	4.5	100
	16Feb2024	10:05	X	0.3	0.3	100
Yes	19Feb2024	10:00		3.6	3.6	99

Varying parameters accross steps

+ Retrieving data for equipment availability, vials inventory, etc

Process Data Standardization Journey



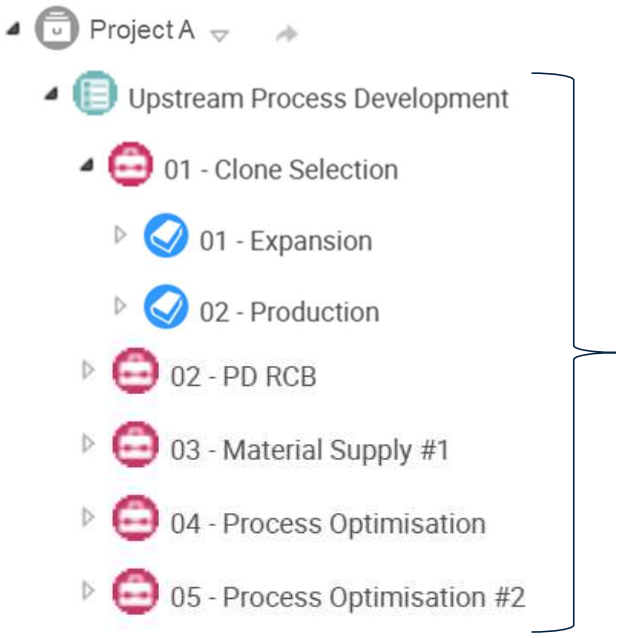
Objectives: Develop a tool at the interface of KBI scientists and customers

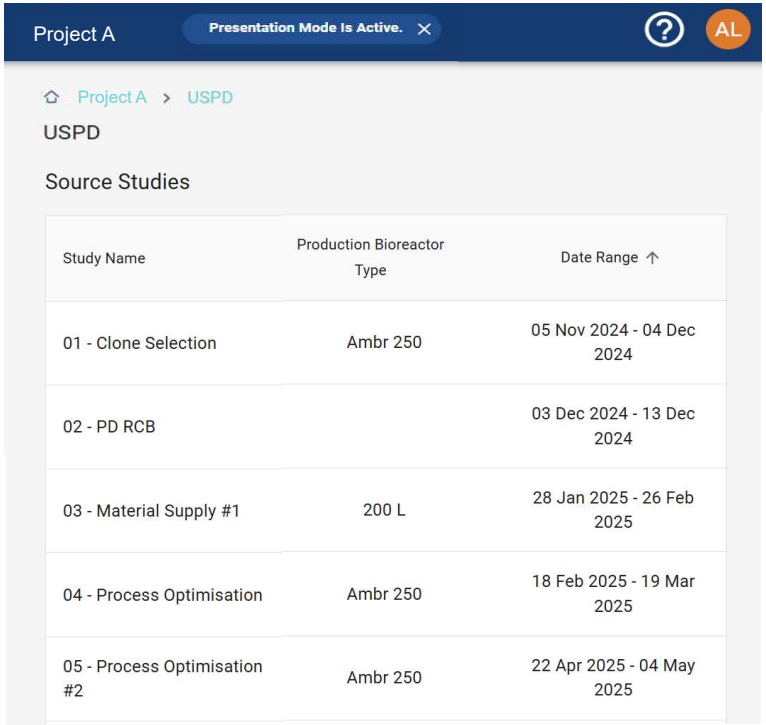
- ❑ One unique interface for the client to follow their project
- ❑ Customer needs focused
- ❑ User-friendly for all types of users
- ❑ Streamline Development Workflow

Process Data Standardization Journey

- Excel-format batch record standardisation
- ELN-based batch record development
- Visualisation Tool development

Data Integration from ELN Spreadsheets:



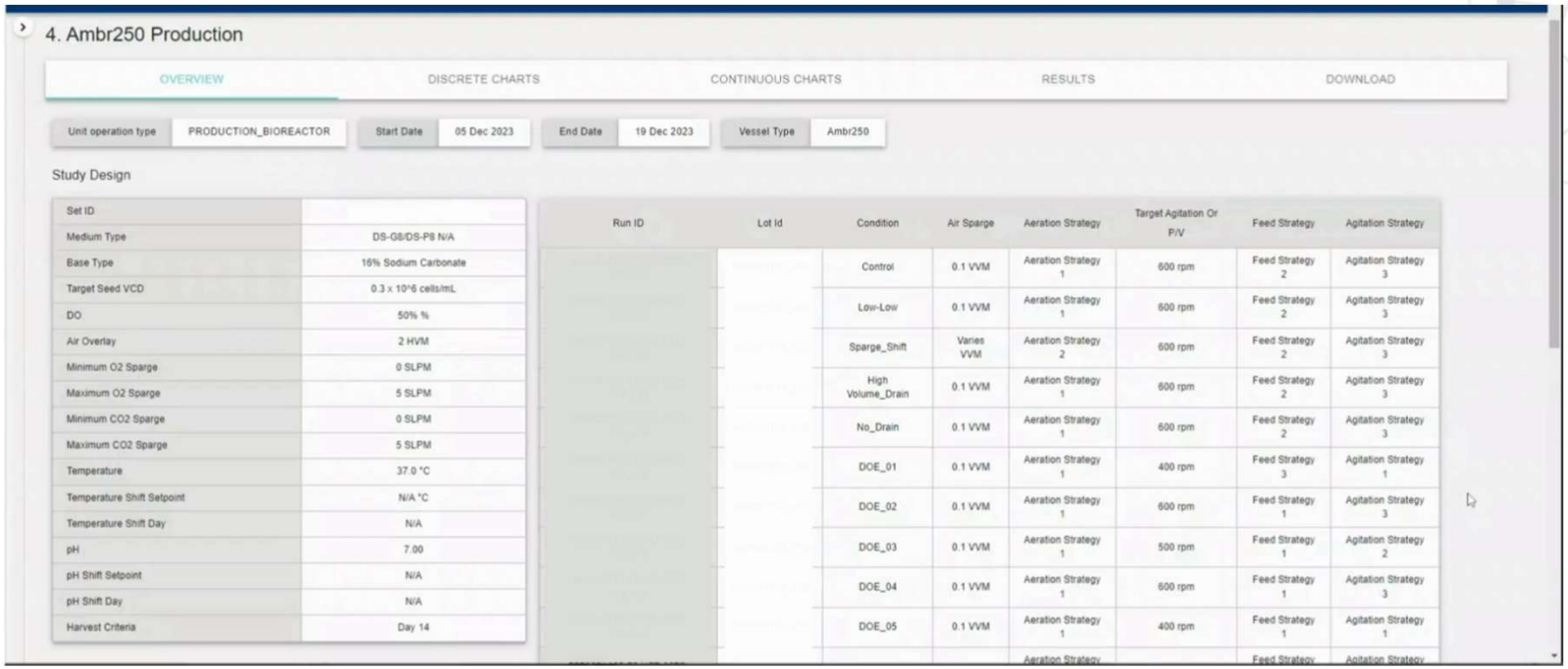


Study Name	Production Bioreactor Type	Date Range
01 - Clone Selection	Ambr 250	05 Nov 2024 - 04 Dec 2024
02 - PD RCB		03 Dec 2024 - 13 Dec 2024
03 - Material Supply #1	200 L	28 Jan 2025 - 26 Feb 2025
04 - Process Optimisation	Ambr 250	18 Feb 2025 - 19 Mar 2025
05 - Process Optimisation #2	Ambr 250	22 Apr 2025 - 04 May 2025

Process Data Standardization Journey

- Excel-format batch record standardisation
- ELN-based batch record development
- Visualisation Tool development

Data Visualization and Analysis from ELN Spreadsheet



4. Ambr250 Production

OVERVIEW | DISCRETE CHARTS | CONTINUOUS CHARTS | RESULTS | DOWNLOAD

Unit operation type: PRODUCTION_BIOREACTOR | Start Date: 05 Dec 2023 | End Date: 19 Dec 2023 | Vessel Type: Ambr250

Study Design

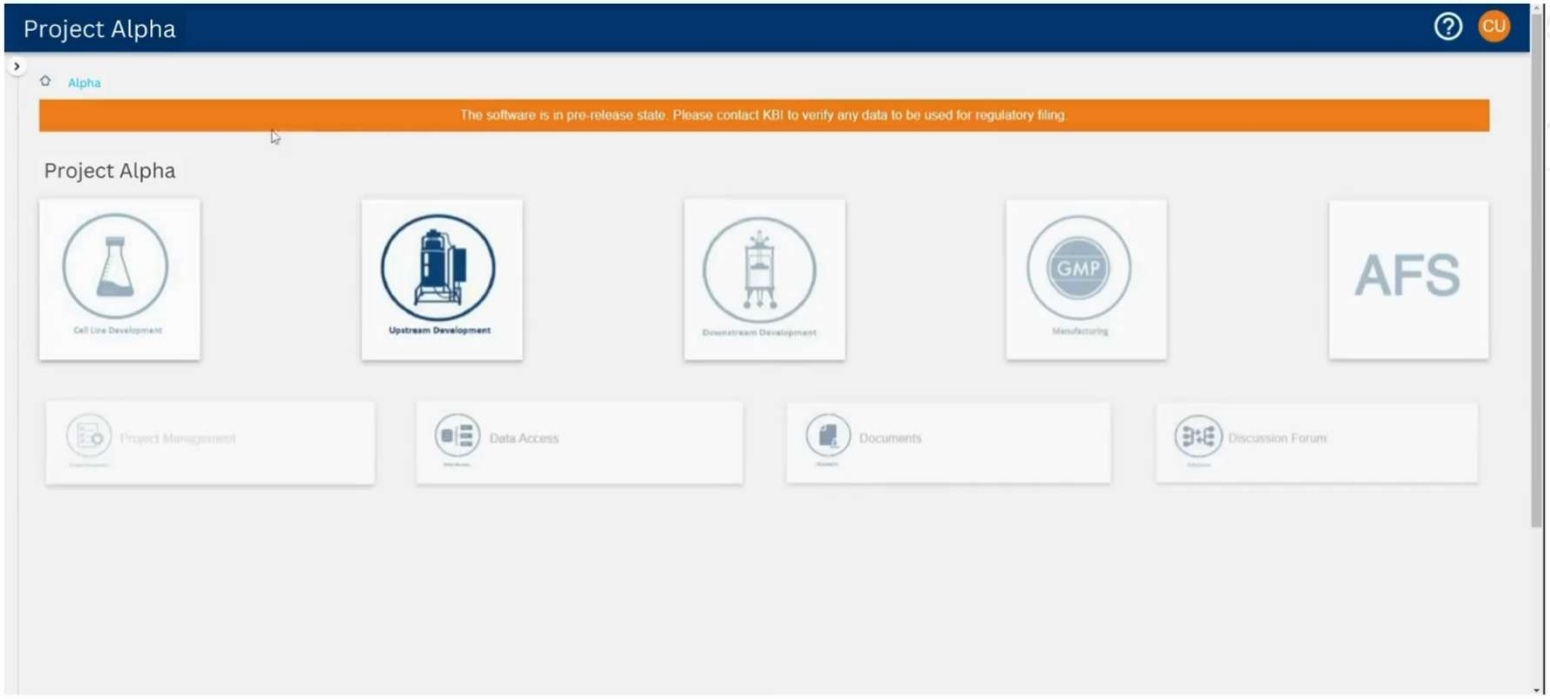
Set ID	
Medium Type	DS-G8/DS-P8 N/A
Base Type	16% Sodium Carbonate
Target Seed VCD	0.3 x 10^6 cells/mL
DO	50% %
Air Overlay	2 HVM
Minimum O2 Sparge	0 SLPM
Maximum O2 Sparge	5 SLPM
Minimum CO2 Sparge	0 SLPM
Maximum CO2 Sparge	5 SLPM
Temperature	37.0 °C
Temperature Shift Setpoint	N/A °C
Temperature Shift Day	N/A
pH	7.00
pH Shift Setpoint	N/A
pH Shift Day	N/A
Harvest Criteria	Day 14

Run ID	Lot Id	Condition	Air Sparge	Aeration Strategy	Target Agitation Or P/V	Feed Strategy	Agitation Strategy
		Control	0.1 VVM	Aeration Strategy 1	600 rpm	Feed Strategy 2	Agitation Strategy 3
		Low-Low	0.1 VVM	Aeration Strategy 1	600 rpm	Feed Strategy 2	Agitation Strategy 3
		Sparge_Shift	Varies VVM	Aeration Strategy 2	600 rpm	Feed Strategy 2	Agitation Strategy 3
		High Volume_Drain	0.1 VVM	Aeration Strategy 1	600 rpm	Feed Strategy 2	Agitation Strategy 3
		No_Drain	0.1 VVM	Aeration Strategy 1	600 rpm	Feed Strategy 2	Agitation Strategy 3
		DOE_01	0.1 VVM	Aeration Strategy 1	400 rpm	Feed Strategy 3	Agitation Strategy 1
		DOE_02	0.1 VVM	Aeration Strategy 1	600 rpm	Feed Strategy 1	Agitation Strategy 3
		DOE_03	0.1 VVM	Aeration Strategy 1	500 rpm	Feed Strategy 1	Agitation Strategy 2
		DOE_04	0.1 VVM	Aeration Strategy 1	600 rpm	Feed Strategy 1	Agitation Strategy 3
		DOE_05	0.1 VVM	Aeration Strategy 1	400 rpm	Feed Strategy 1	Agitation Strategy 1

Process Data Standardization Journey

- Excel-format batch record standardisation
- ELN-based batch record development
- Visualisation Tool development

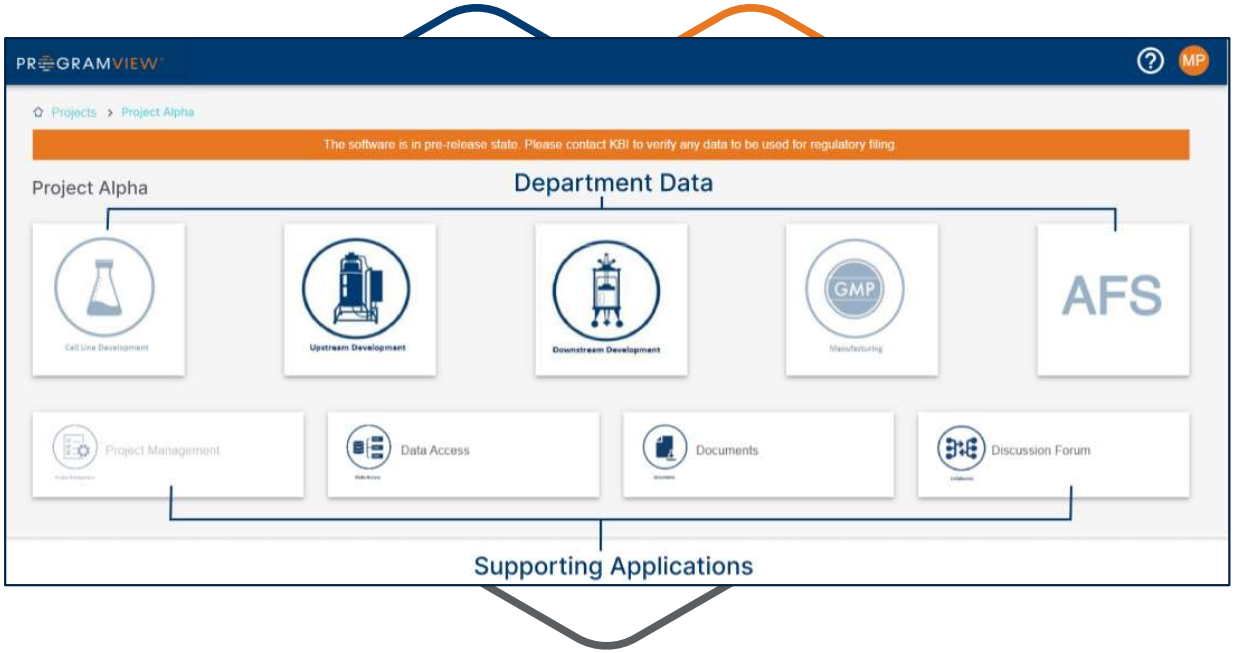
Communication Platform:



Process Data Standardization Journey

- Excel-format batch record standardisation
- ELN-based batch record development
- Visualisation Tool development
- Program View launch

PROGRAMVIEW™

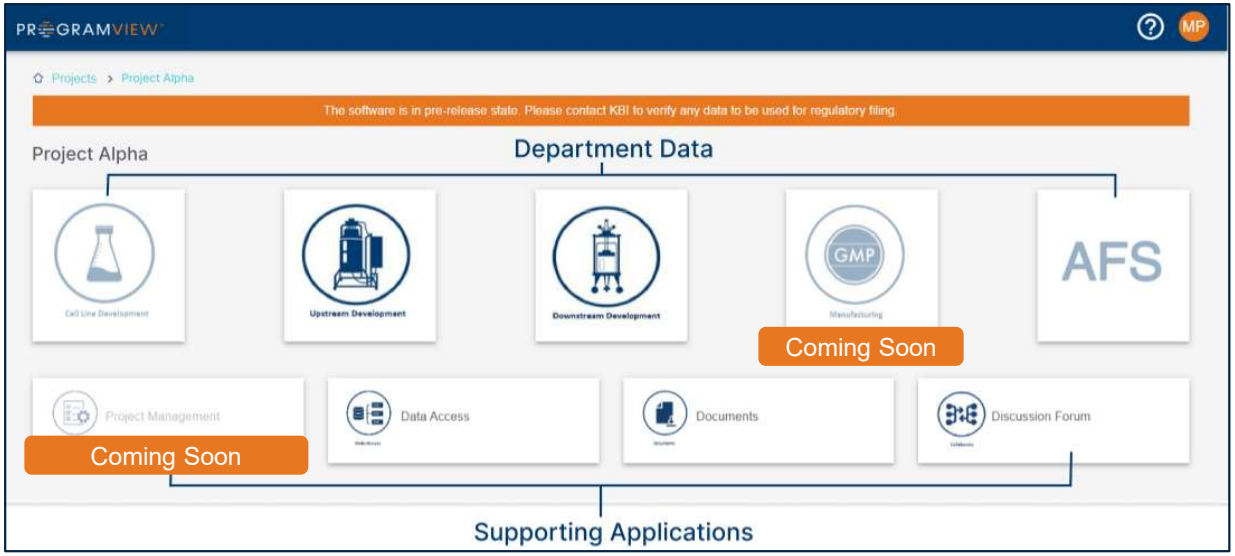


→ Officialy launched in 2024
→ In total, more than 200 programs and 800 Customer users enrolled

Process Data Standardization Journey

- Excel-format batch record standardisation
- ELN-based batch record development
- Visualisation Tool development
- Program View launch
- Continuous improvment

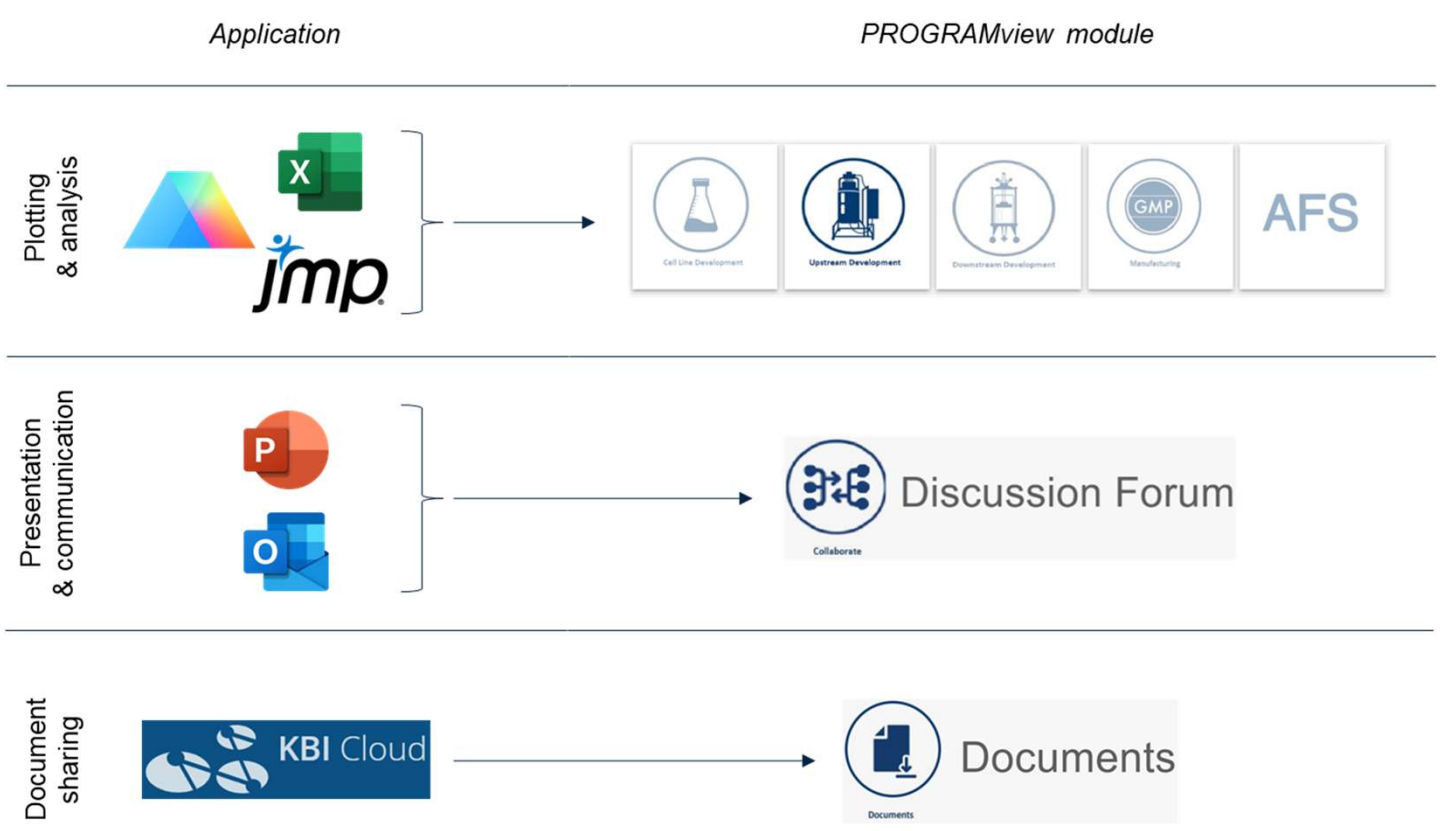
PROGRAMVIEW™



Internal Updates

Links between lab equipment and ELN Spreadsheet

New Workflow with ProgramView



At least 5% time saved for the upstream process development team

Scientist Extra-Time + Data accessibility

Potential for further data leveraging

Next Steps for Upstream Process Development

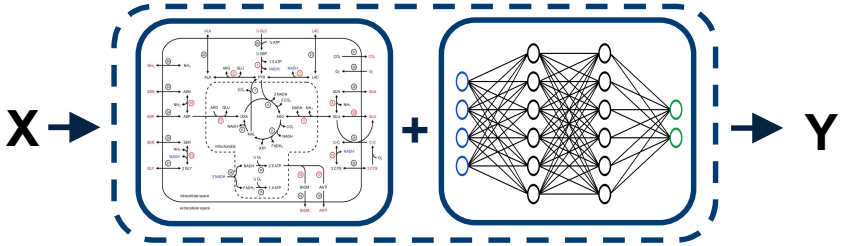
What we Need:

- ❑ Shorter Timelines → Shorter time to Market
- ❑ Lower Cost → Decrease overall Development cost and improve competitivity
- ❑ Processes with similar to better quality

What we Have:

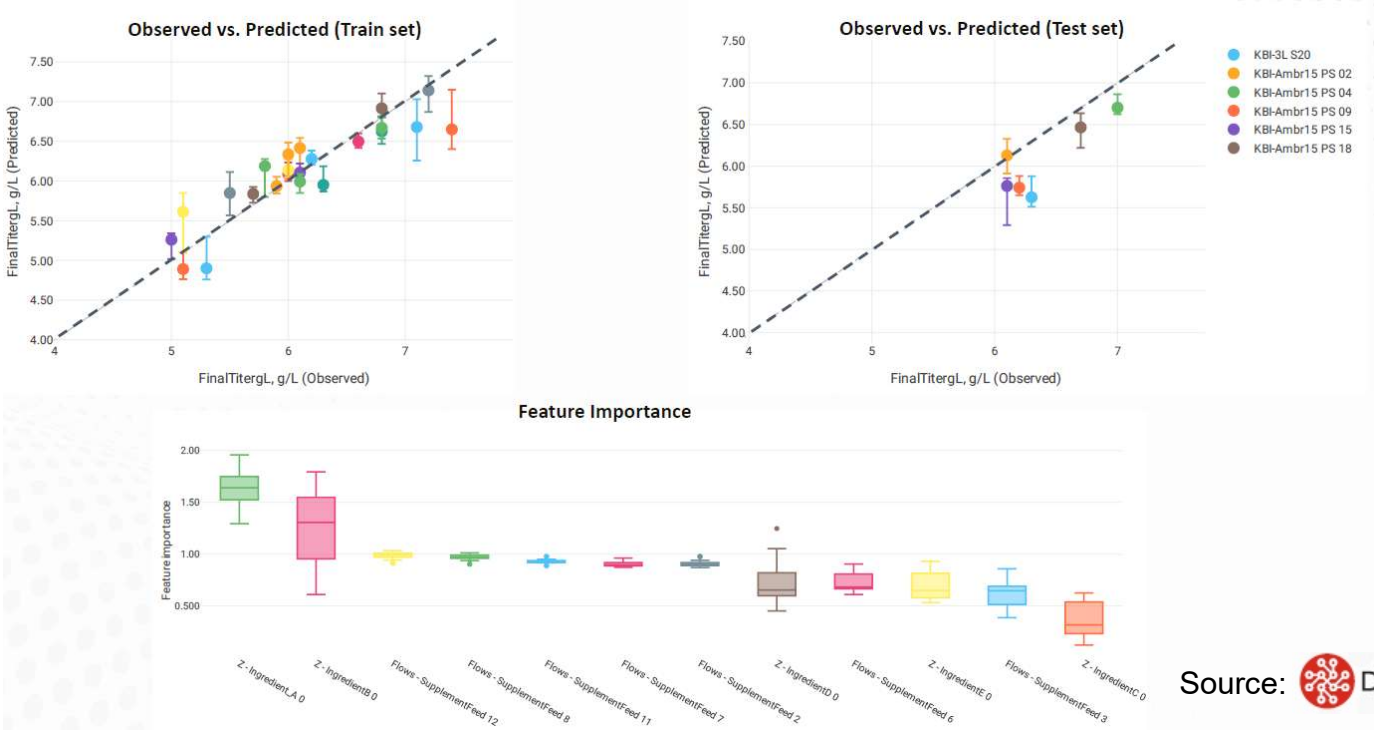
- ❑ Data Quantity
- ❑ Data Variety
- ❑ Standardized and accessible data

What we Selected: **Transfer Learning and In-silico Prediction via Hybrid modelling**



Hybrid modelling: Next Journey to come

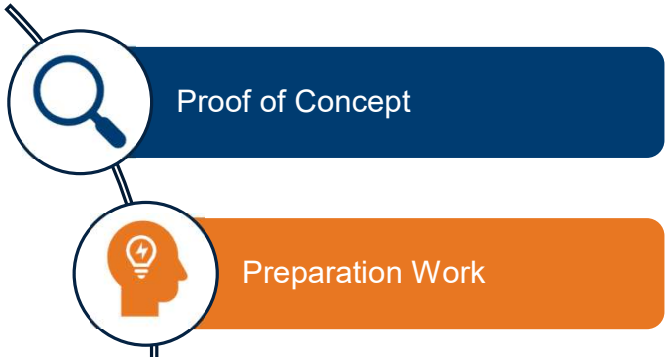
Proof of Concept



Source: DATAHOW

→ Similar conclusions were drawn between Hybrid and DOE models
→ Demonstrated a possible run reduction until 40 % to predict process results

Hybrid modelling: Next Journey to come



Identification of key variable for:

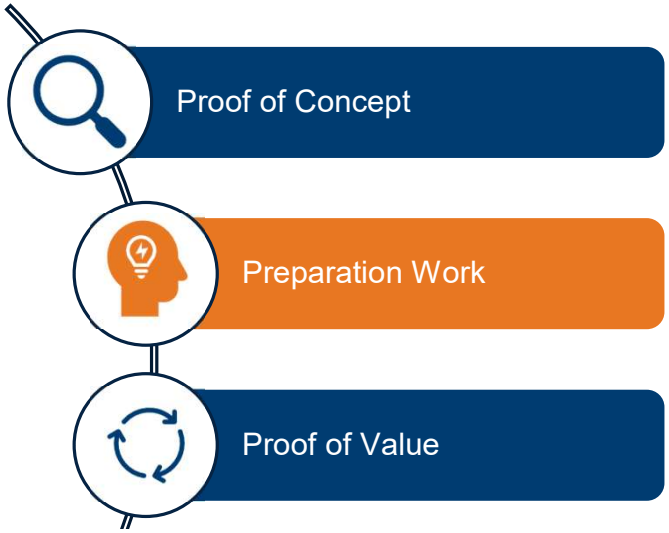
- ❑ Data Sorting
- ❑ Data Visualisation
- ❑ Data Modelling

Connector between KBI Database and DataHowLab

Future Strategies:

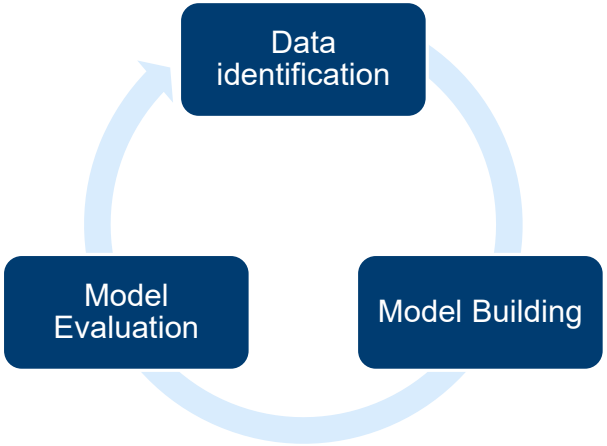
- ❑ Transfer Learning (productivity, product quality, early prediction)
- ❑ Improve scalability robustness (Process characterisation, Large scale Digital Twins)

Hybrid modelling: Next Journey to come



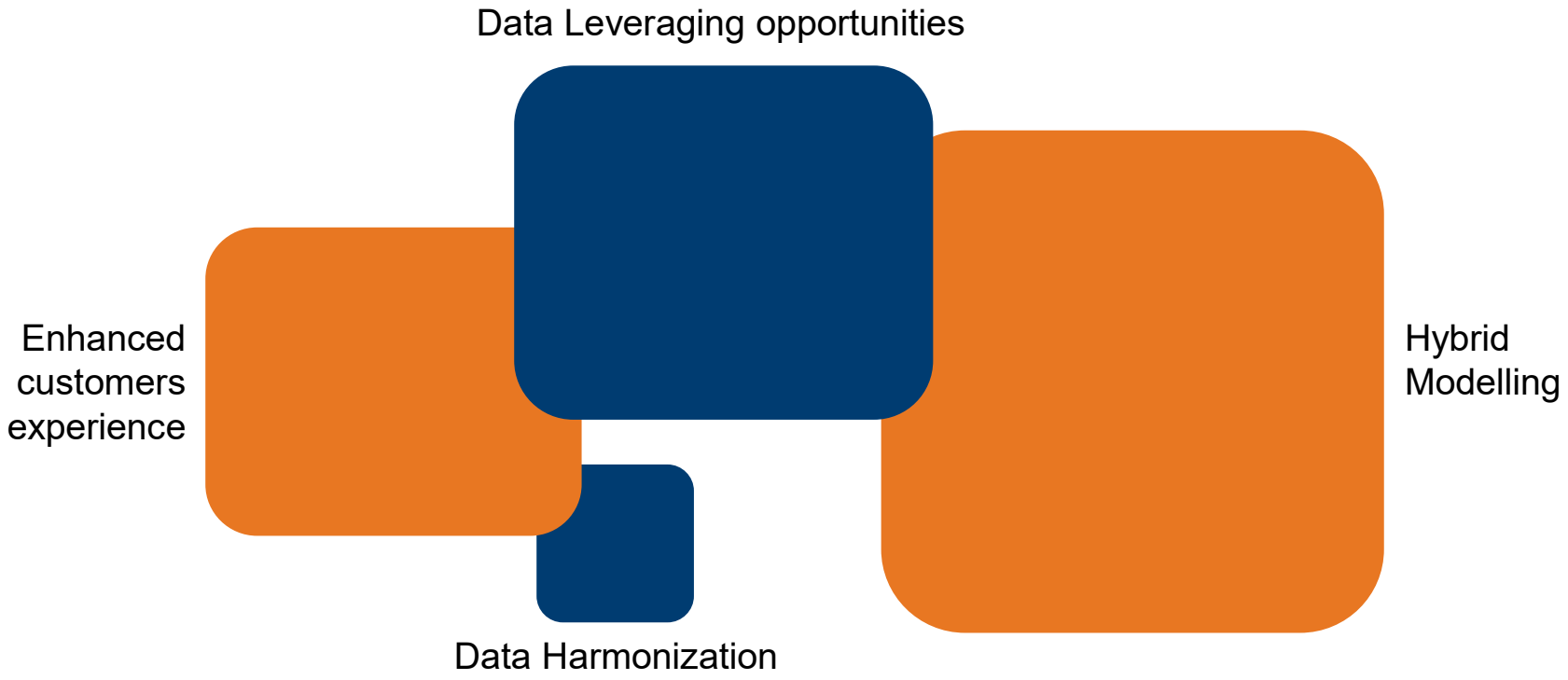
<u>For each Strategy:</u>

- Model Development



- Proof of value on one client project

Take Home Message



Acknowledgements

- ProgramView Product Owner – Marlee Paulson
- ProgramView Support Team
- DataHow Team
- Our Customers
- KBI Upstream Process Development

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A JSR Life Sciences Company

Science Driven. Customer Focused.

A Global CDMO Providing Innovative Biologic Solutions

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