

Think forward

Fueling innovation with transformative intelligence, from research and learning to commercialization



Enriched data

Selected and enhanced by domain experts and data scientists



Insights and analytics

Driven by AI-enabled platforms paired with human expertise



Workflow solutions

Flexible software tools tailored to meet your needs



Expert services

Industry specialists with deep expertise and global experience

Data

600+
Years of historical
content

9,000+
Content providers

2.5+ billion
Citations

600,000+
Clinical trials

300+ million
Real world data
patient records

59+ million
Inventions

9.1+ million
IP law cases

140+ million
Trademark records

Customers

99%
Top 400 universities¹

100%
Top Pharma,
Biotech, Medtech²

75%
National & regional
research assessments

96%
Top 50 companies
by R&D spend³

90%
Top 10 brands⁴

Expertise

11,500+
professionals

40
countries

150+
Years of heritage

Top 100 Global
Innovators™

Drugs to Watch™

Highly Cited
Researchers™

2024 Revenue
~\$2.4B

¹ Top 400 universities (QS world university rankings). ² Top 30 pharma (Drug Discovery Trends). Top 20 medical device (Greenlight Guru). Top 10 biotech (Investopedia). ³ Top 50 based on R&D spend (European Union). ⁴ Source: Best Global Brands - The 100 Most Valuable Global Brands (interbrand.com)



Medical Device Summit 2025



JOHN LEAMY

VP, Quality Systems and Digital Services
Johnson & Johnson



JOHN PEYTON

VP, Customer Success
Clarivate Analytics

AI-DRIVEN PRODUCTIVITY IN QUALITY: CROSS SEGMENT PERSPECTIVES

Advancing Quality & Compliance

HARNESSING GENERATIVE AI
TO DIGITIZE YOUR QUALITY
MANAGEMENT SYSTEM

John Leamy
Oct 28th 2026

Johnson & Johnson
MedTech

Quality & Compliance



Medical Device Summit 2025

Optimizing Human
Potential

Mitch Hayes, Senior Vice President, General Manager

28th October 2025

28th October 2025



Medical Device Summit 2025

Optimizing Human Potential

Mitch Hayes, Senior Vice President, General Manager

28th October 2025

My Journey...

3 Companies, 35 Years



30 Years
Ago



8 Years
Ago



Today

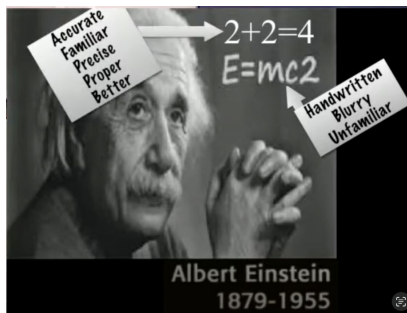
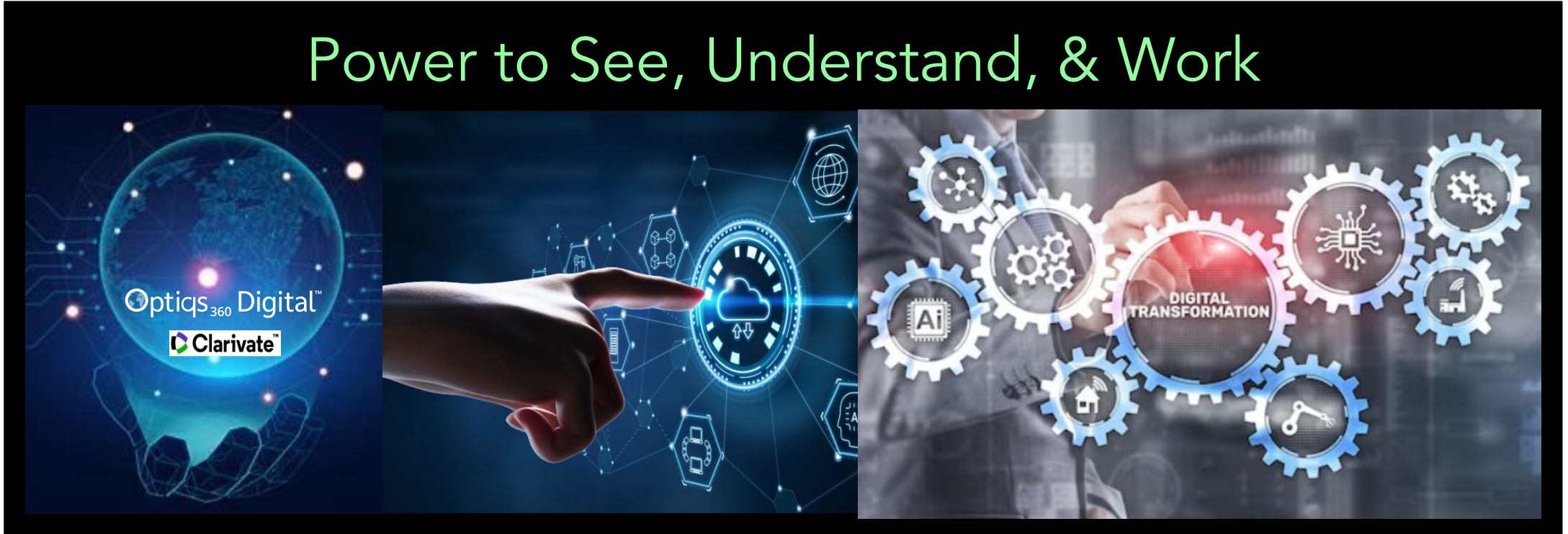
– Same Mission –
Data Visibility and Work Facilitation

My Journey...

Data Visibility and Work Facilitation



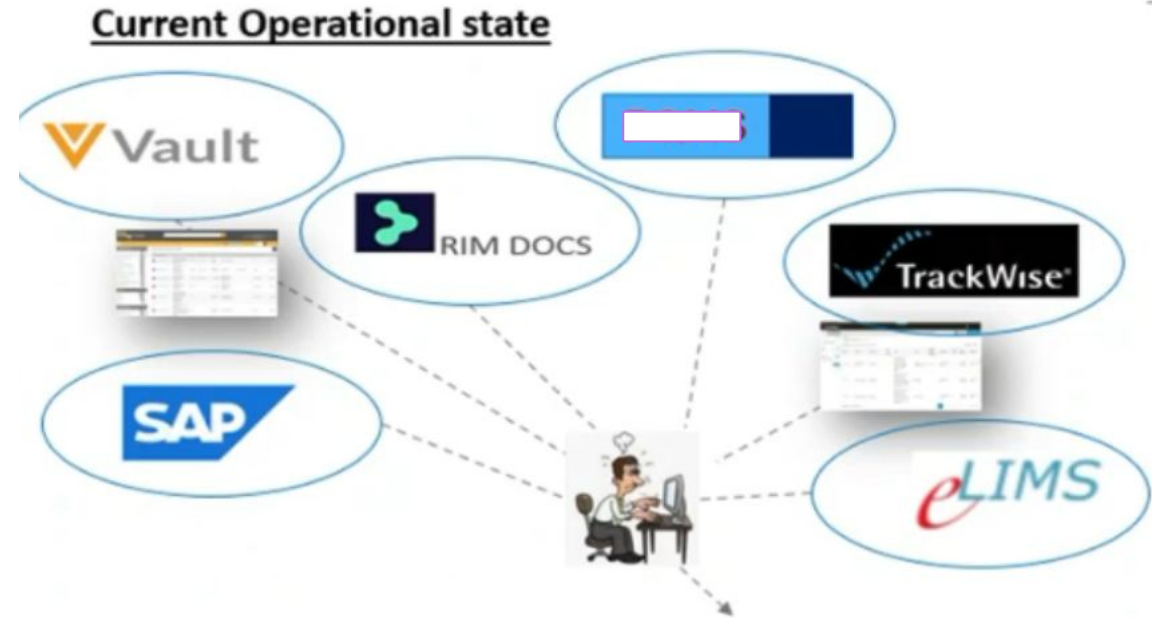
Power to See, Understand, & Work



Operational Efficiency

Problem Observed:

- **Fragmented Data Ecosystems:** Critical information is scattered across R&D, clinical, manufacturing, and post-market systems, making it difficult to generate a single source of truth and slowing decision-making in drug development and commercialization.

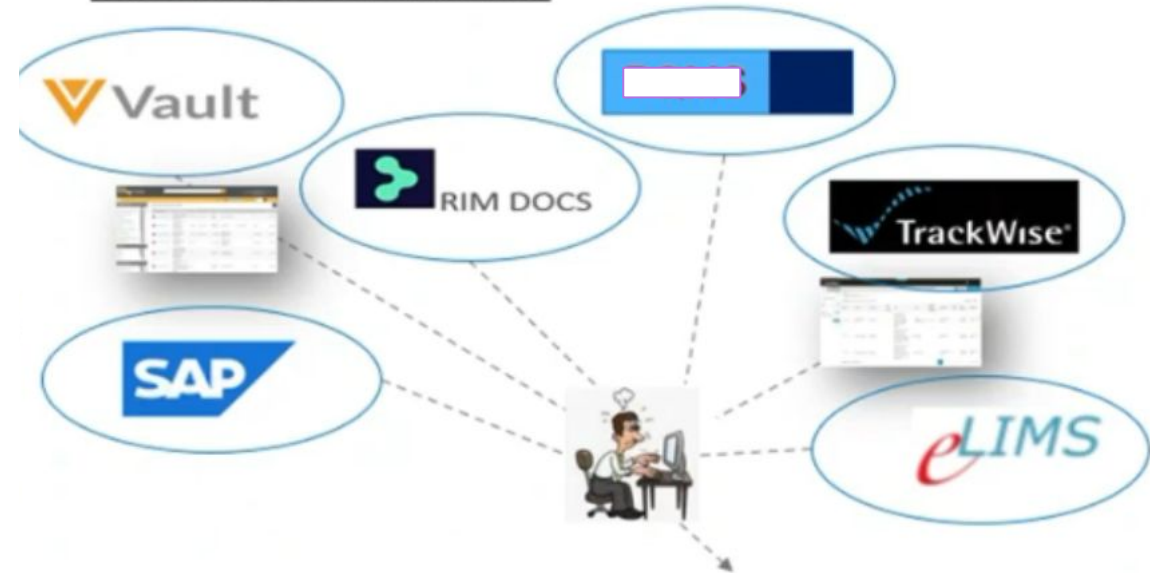


Operational Efficiency

Problem Observed:

- **Fragmented Data Ecosystems:** Critical information is scattered across R&D, clinical, manufacturing, and post-market systems, making it difficult to generate a single source of truth and slowing decision-making in drug development and commercialization.
- **Manual, Redundant Processes:** Teams spend significant time on repetitive tasks like data reconciliation, reporting, and compliance checks, diverting focus from innovation and increasing the risk of human error.

Current Operational state

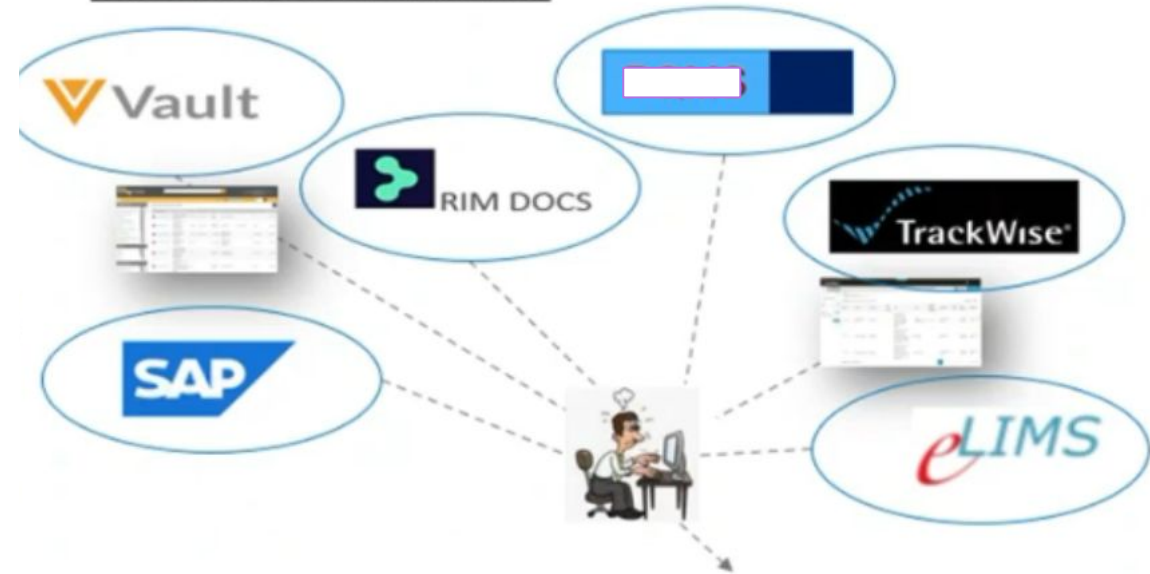


Operational Efficiency

Problem Observed:

- **Fragmented Data Ecosystems:** Critical information is scattered across R&D, clinical, manufacturing, and post-market systems, making it difficult to generate a single source of truth and slowing decision-making in drug development and commercialization.
- **Manual, Redundant Processes:** Teams spend significant time on repetitive tasks like data reconciliation, reporting, and compliance checks, diverting focus from innovation and increasing the risk of human error.
- **Compliance and Traceability Risks:** Inconsistent data and lack of standardized processes create vulnerabilities in regulatory audits, leading to potential delays, costly remediation, and reputational damage.

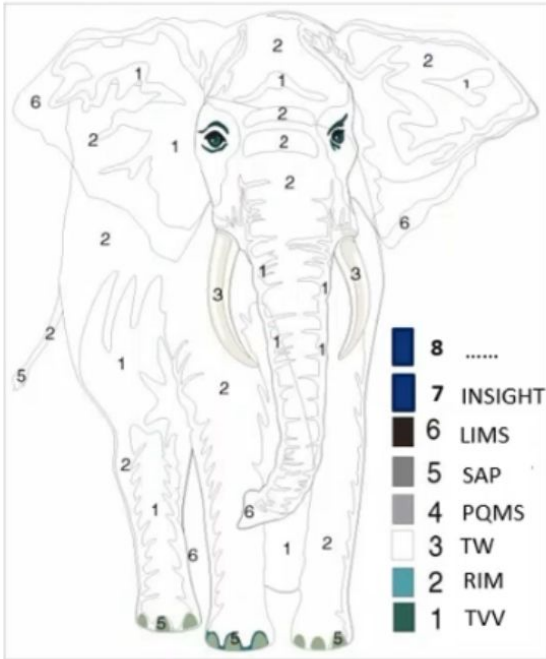
Current Operational state



Operational Efficiency

Problem Observed:

FRAGMENTED VIEW



Fragmented Insight of Product “data” in multiple systems

Access to each system (to get data) is burdened by:

Training Requirements

License Cost Requirements

A different UI for each system

Source system changes or replacement

Many others...

Data Organization (for easy reference and reuse) is burdened by:

Different styles of data organization

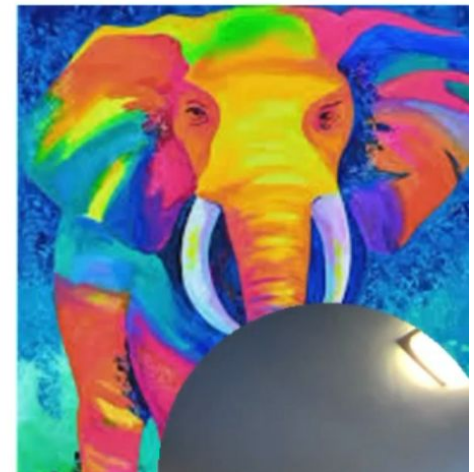
Different applications used for data organization

Different degree of “completeness” of data organization

All contributing factors to Operational Efficiency!



COMPOSITE VIEW



Vision for helping improve conditions

External Data Streams



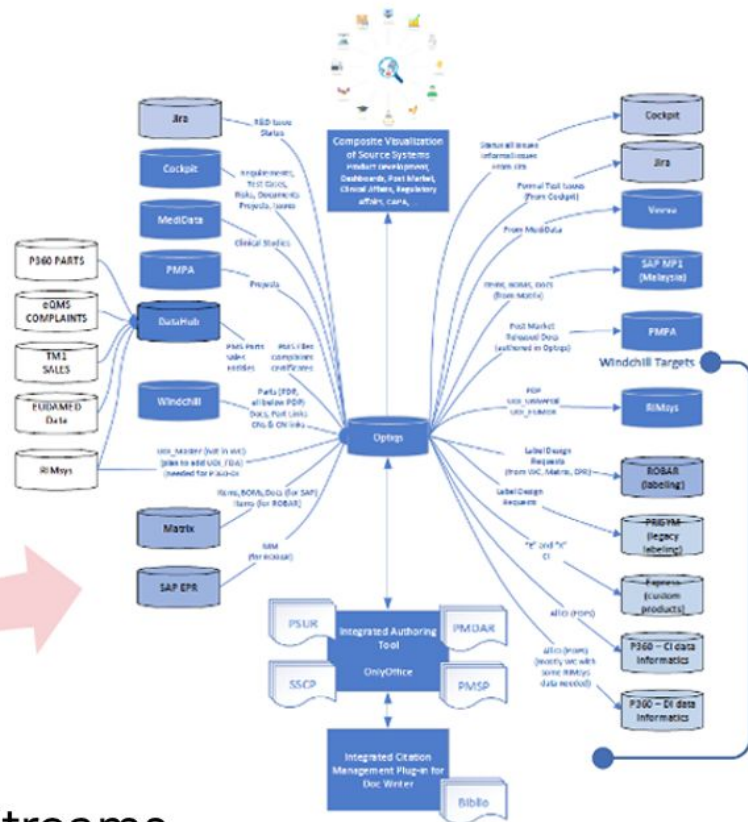
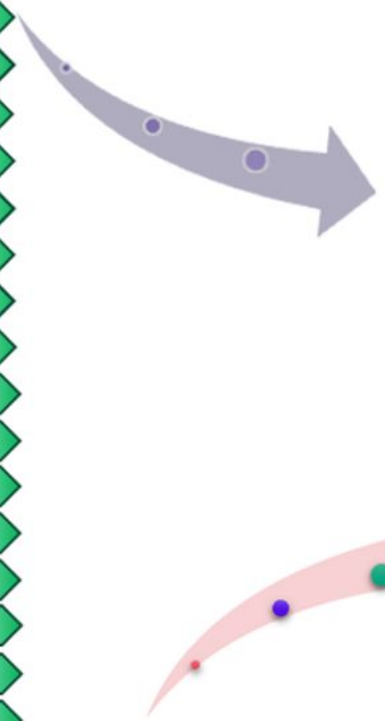
Internal Data Streams



Vision for helping improve conditions

External Data Streams

- Cortellis Reg Intelligence
- Cortellis HTA Intelligence
- PV & Drug Safety
- OFF-X
- BioWorld
- MedTech 360
- Market Intelligence Data
- DRG Policy Tracker
- Cortellis Drug Discovery
- Epidemiology
- Cortellis Competitive Intel
- Patient Journey
- Web of Science
- Real World Data
- Drug Safety Triager
- Med Lit Monitoring
- Dialog



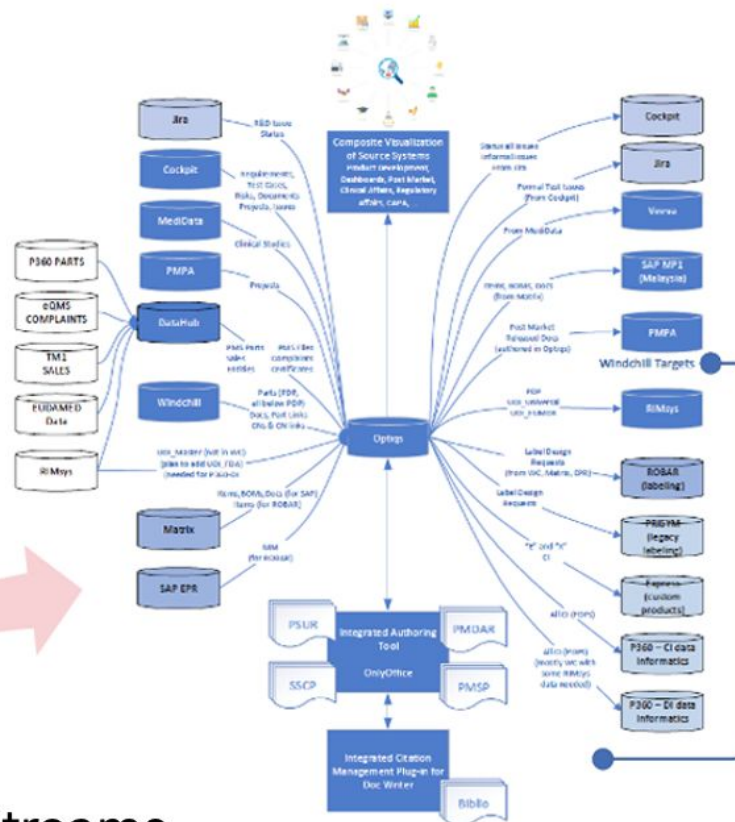
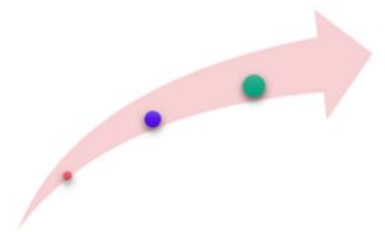
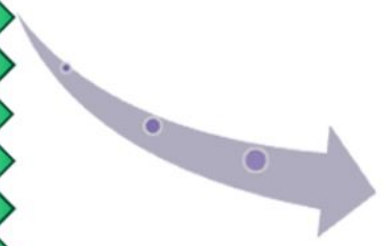
Internal Data Streams



Vision for helping improve conditions

External Data Streams

- Cortellis Reg Intelligence
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- MedTech 360
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- Cortellis Drug Discovery
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- Drug Safety Triager
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Internal Data Streams



Vision for helping improve conditions

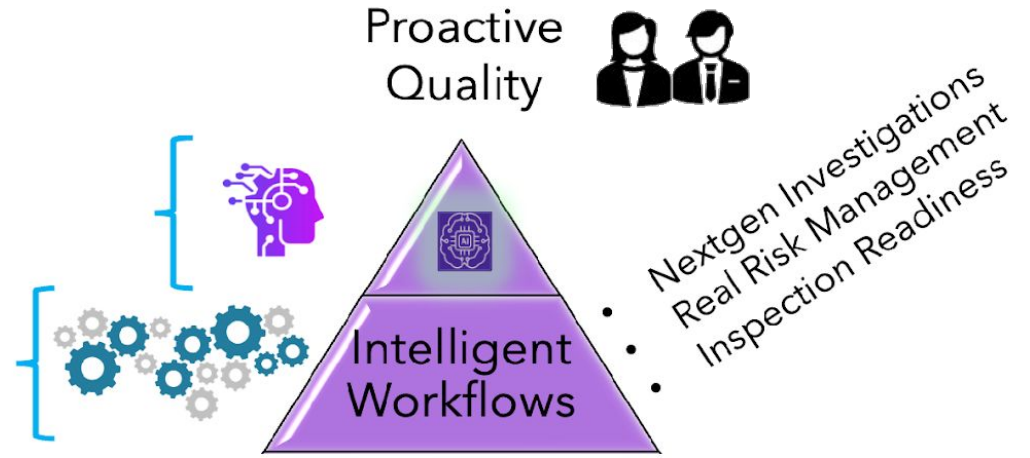
5. Agents working on Insights, Triggers, & Responses



Vision for helping improve conditions

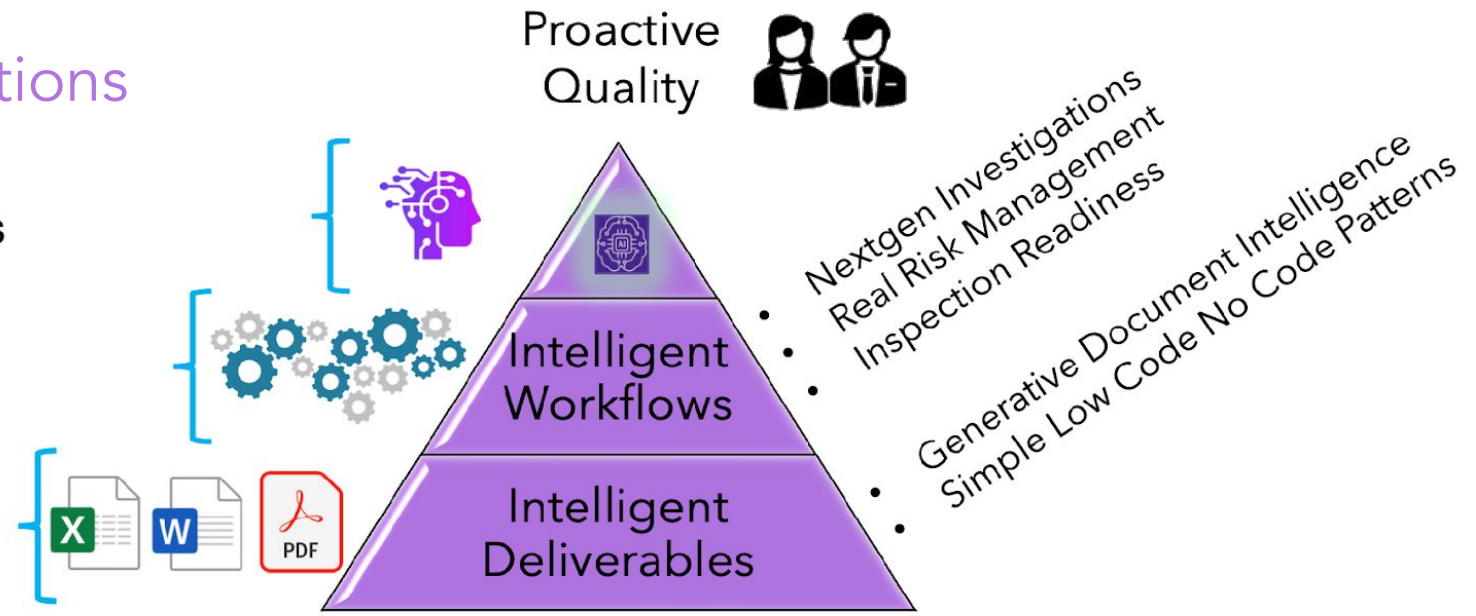
5. Agents working on Insights, Triggers, & Responses

4. Agents working on Work Process/Guidelines



Vision for helping improve conditions

- 5. Agents working on Insights, Triggers, & Responses
- 4. Agents working on Work Process/Guidelines
- 3. Agents working on Deliverables/Artifacts



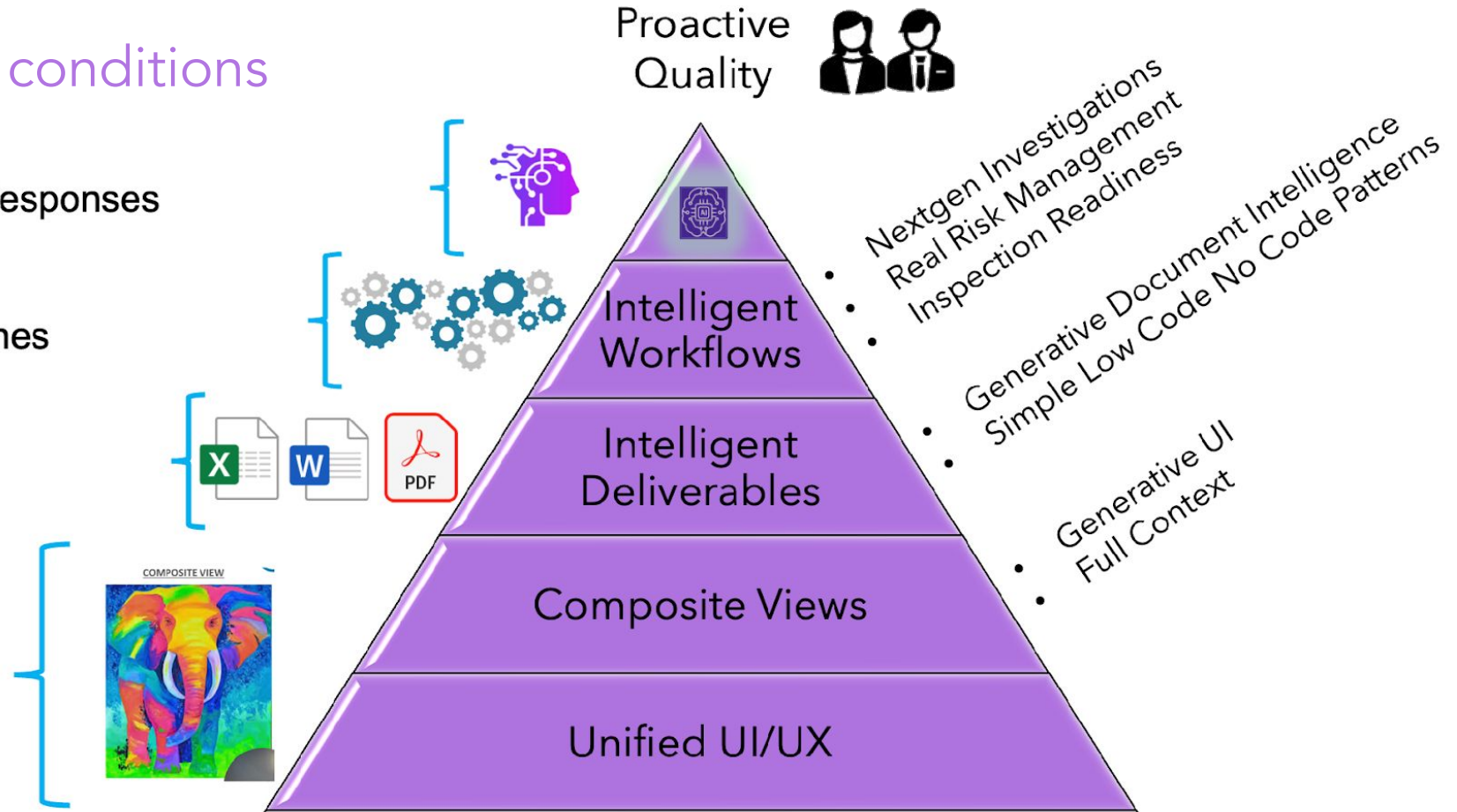
Vision for helping improve conditions

5. Agents working on Insights, Triggers, & Responses

4. Agents working on Work Process/Guidelines

3. Agents working on Deliverables/Artifacts

2. Agents working on Composite UI/UX



Vision for helping improve conditions

Proactive Quality 

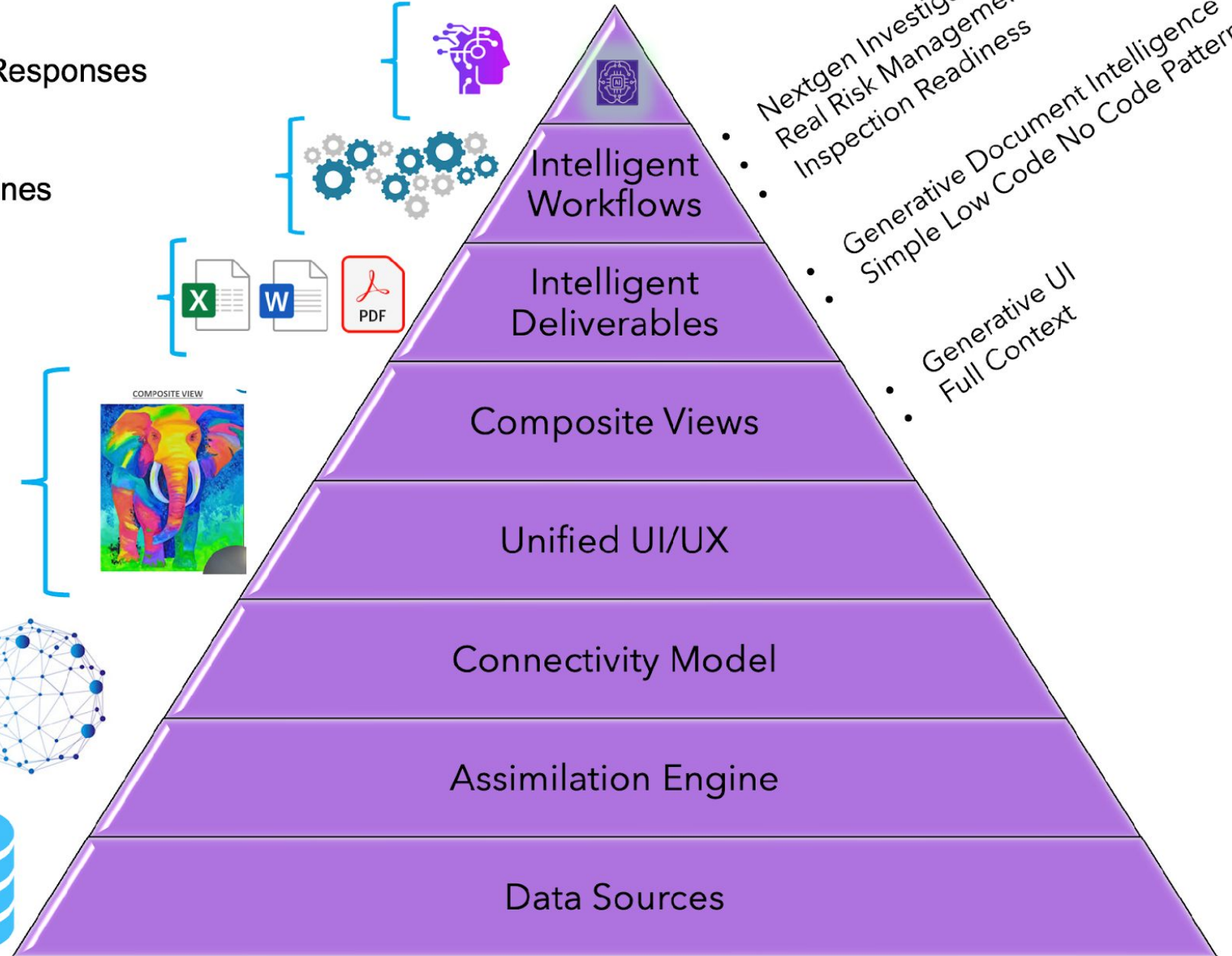
5. Agents working on Insights, Triggers, & Responses

4. Agents working on Work Process/Guidelines

3. Agents working on Deliverables/Artifacts

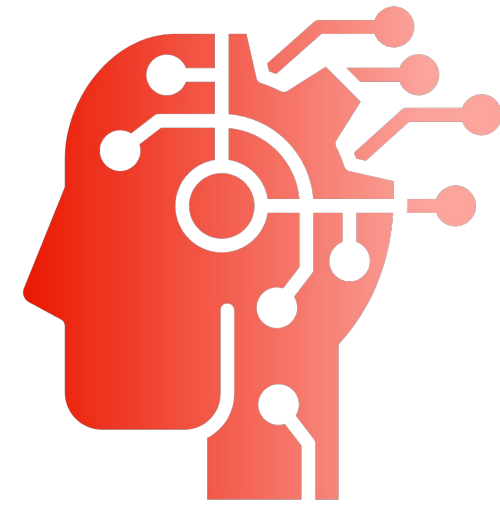
2. Agents working on Composite UI/UX

1. Agents working on the Data





What could it look like?





Type Experts [refresh] [filter]

Name ↑	Assigned to Human	Creation Date	State	Last Modified By	Last Modified Date	Inherits from Expert of
- Application Main Workers		06/16/2025 11:58	In Work		06/23/2025 16:51	IM 360 1.0
IM:Foreign Data (XF)		06/16/2025 12:07	In Work		06/30/2025 10:14	Application Main Workers
+ IM:Object		06/16/2025 12:02	In Work		06/26/2025 07:36	Application Main Workers
IM:View Data (XD)		06/16/2025 12:07	In Work		06/26/2025 07:34	Application Main Workers
- COMET Workers		06/23/2025 11:49	In Work		06/23/2025 11:49	IM 360 1.0
COMET Account		06/23/2025 14:29	In Work		06/23/2025 14:30	COMET Workers
+ COMET Action Base		06/23/2025 12:00	In Work		06/23/2025 12:00	COMET Workers
+ COMET Action Plan Base		06/23/2025 14:55	In Work		06/23/2025 14:55	COMET Workers
COMET Assessment		06/23/2025 14:59	In Work		06/23/2025 14:59	COMET Workers
COMET Assessment Execution		06/23/2025 12:18	In Work		06/23/2025 12:19	COMET Workers
COMET Audit		06/23/2025 14:20	In Work		06/23/2025 15:46	COMET Workers
COMET Audit Observation		06/23/2025 14:26	In Work		06/23/2025 14:28	COMET Workers
COMET CAPA		06/23/2025 14:33	In Work		06/23/2025 14:34	COMET Workers
COMET ChangeControl		06/23/2025 14:35	In Work		06/23/2025 14:36	COMET Workers
COMET Containment		06/23/2025 14:38	In Work		06/25/2025 13:42	COMET Workers
COMET Correction		06/24/2025 12:28	In Work		06/24/2025 12:30	COMET Workers
COMET Corrective Action		06/24/2025 12:28	In Work		06/24/2025 12:30	COMET Workers
COMET Escalation		06/23/2025 15:23	In Work		06/23/2025 15:23	COMET Workers
COMET Finding		06/23/2025 15:01	In Work		06/23/2025 15:01	COMET Workers
COMET Immediate Cause		06/23/2025 15:02	In Work		06/23/2025 15:02	COMET Workers
COMET Implementation		06/23/2025 15:03	In Work		06/23/2025 15:03	COMET Workers
COMET Interim Control		06/23/2025 14:39	In Work		06/23/2025 15:50	COMET Workers
+ COMET Investigation Base		06/23/2025 15:05	In Work		06/23/2025 15:05	COMET Workers
COMET Laboratory Investigation		06/23/2025 15:06	In Work		06/23/2025 15:07	COMET Workers
COMET Meeting		06/23/2025 15:00	In Work		06/23/2025 15:00	COMET Workers
COMET NC Risk Assessment		06/23/2025 14:44	In Work		06/25/2025 13:43	COMET Workers
COMET Nonconformance		06/23/2025 15:26	In Work		06/23/2025 15:26	COMET Workers
Comet Object		06/26/2025 09:41	In Work		06/26/2025 09:41	COMET Workers
COMET Preventive Action		06/24/2025 12:28	In Work		06/24/2025 12:30	COMET Workers
COMET Root Cause		06/23/2025 15:28	In Work		06/23/2025 15:28	COMET Workers

264 items 1 selected

Agents in Charge of Leveraging their Structured Data as well Unstructured Content.



Type Experts + ↺ ⌵

Name

LOC

- GRAInsight Workers
 - GRAInsight View Data
 - XD GRAInsight Regulatory LOC Product

3 items 1 selected

XD GRAInsight Regulatory LOC Product State: In Work, Version: 0.1.1 - Checked Out t

📄 Résumé & Properties
🟢 Commands Offered
🔗 AI/ETL Skills Available
📄 Helper Definitions
👤 Responsibilities

Type Expert: XD GRAInsight Regulatory LOC Proc

Creation Date: Jun 26 2025 09:36:14 am

State: In Work

Version: 0.1

Inherits from Expert of: GRAInsight View Data

With resumes.

Résumé/Description

B / U A | 🔍 🔧 📄 🔗 📄 +

You are an expert in text analysis and natural language processing employed to match product records in the Pharma industry, within the following context:

- Set #1 and set #2 contain data that is believed to belong to the same entities, which are recorded in different ways.
- In the next layer of details, please know that the strings in each record will possibly, but not necessarily contain information about
 - Names of countries where the pharma products are sold, written with several variations of lower and upper case. Moreover, names may be abbreviated, grouped with names/abbreviations of other countries within the same geographic area, or replaced by a region/sub-region descriptor altogether;
 - Commercial names of the pharma products, written with several variations of lower and upper case;
 - presentation (for example: "tablet" or "TBLT," for tablets, in addition to "capsules" or "caps." for capsules), with several variations of lower and upper case;
 - dosage, with numeric values and units such as "MG", "ML", "MG/ML", with several variations of upper and lower case;
 - counts, such as "10 count x 3 blisters in wallet (30 count)" or "30 TABL." and
 - Administration methods, such as "injection in pre-filled syringe" and "Prolonged-release capsule".

Once you understand each record per the breakdown above, you will:

- Crte an output in .JSON format containing the following fields for each record:
 - Country/Region/Sub-region;
 - Medication commercial name;
 - Presentation;
 - Dosage;
 - Counts and f) Administration method.

Additional Information

Data Source:

Server Class:



Data Type Agent + - ↺ ↻ ⌵ ⌶ ⌷

Name ↑	Creation Date	State	Last Modified Date	Inherits from Expert of
🔗 PQM Product Attribute	06/23/2025 12:45	In Work	06/23/2025 12:45	👥 PQM Workers
🔗 PQM Product Family	06/23/2025 15:17	In Work	06/23/2025 15:18	👥 PQM Workers
🔗 PQM Product Family Attribute	06/23/2025 12:48	In Work	06/23/2025 15:19	👥 PQM Workers
+ 🔗 PQM View Data	06/26/2025 09:40	In Work	06/26/2025 09:41	👥 PQM Workers
- 👥 PQMS Workers	06/23/2025 13:52	In Work	06/23/2025 13:52	🏠 IM 360 1.0
🔗 PQMS Complaint	06/23/2025 14:46	In Work	06/23/2025 14:46	👥 PQMS Workers
🔗 PQMS Complaint Attribute	06/23/2025 14:04	In Work	06/23/2025 14:04	👥 PQMS Workers
🔗 PQMS Investigation	06/23/2025 15:08	In Work	06/23/2025 15:59	👥 PQMS Workers
🔗 PQMS Object	06/26/2025 09:47	In Work	06/26/2025 09:47	👥 PQMS Workers
+ 🔗 PQMS View Data	06/26/2025 09:48	In Work	06/26/2025 09:48	👥 PQMS Workers
- 👥 QEM Info Workers	06/26/2025 09:49	In Work	06/26/2025 09:49	🏠 IM 360 1.0
🔗 QEM Info Object	06/26/2025 09:49	In Work	06/26/2025 09:49	👥 QEM Info Workers
+ 🔗 QEM View Data	06/26/2025 09:50	In Work	06/26/2025 09:50	👥 QEM Info Workers
- 👥 RIMDocs Workers	06/23/2025 13:53	In Work	06/23/2025 13:53	🏠 IM 360 1.0
🔗 RIMDocs Object	06/26/2025 09:51	In Work	06/26/2025 09:51	👥 RIMDocs Workers
🔗 RIMDocs Record Attribute	06/23/2025 14:10	In Work	06/23/2025 14:11	👥 RIMDocs Workers
+ 🔗 RIMDocs View Data	06/26/2025 09:51	In Work	06/26/2025 09:52	👥 RIMDocs Workers
- 👥 SAP Workers	06/26/2025 07:28	In Work	06/26/2025 07:28	🏠 IM 360 1.0
🔗 SAP Object	06/26/2025 07:30	In Work	06/26/2025 07:30	👥 SAP Workers
- 🔗 SAP View Data	06/26/2025 07:41	In Work	06/26/2025 07:42	👥 SAP Workers
🔗 XD SAP Batch Details Info	06/26/2025 08:32	In Work	06/26/2025 08:32	🔗 SAP View Data
🔗 XD SAP DNA BLUECRUX PRODUCTS Info	06/26/2025 08:31	In Work	06/26/2025 08:31	🔗 SAP View Data
🔗 XD SAP DNA BLUECRUX SCNODES Info	06/26/2025 08:31	In Work	06/26/2025 08:31	🔗 SAP View Data
🔗 XD SAP FG Batch Details Info	06/26/2025 08:31	In Work	06/26/2025 08:31	🔗 SAP View Data
🔗 XD SAP MATERIAL BATCH FLOWS Info	06/26/2025 07:44	In Work	06/26/2025 07:44	🔗 SAP View Data
- 👥 Trackwise Workers	06/23/2025 11:50	In Work	06/23/2025 11:50	🏠 IM 360 1.0
🔗 TrackWise Assessment Plan	06/23/2025 12:20	In Work	06/23/2025 12:20	👥 Trackwise Workers
🔗 TrackWise Audit	06/23/2025 14:25	In Work	06/23/2025 14:25	👥 Trackwise Workers
🔗 TrackWise Audit Attribute	06/23/2025 12:33	In Work	06/23/2025 12:33	👥 Trackwise Workers
🔗 TrackWise Auditee	06/23/2025 14:31	In Work	06/23/2025 14:31	👥 Trackwise Workers
🔗 TrackWise Auditee Attribute	06/23/2025 12:34	In Work	06/23/2025 12:35	👥 Trackwise Workers
🔗 TrackWise CAPA	06/23/2025 14:34	In Work	06/23/2025 14:34	👥 Trackwise Workers
🔗 TrackWise CAPA Attribute	06/23/2025 12:37	In Work	06/23/2025 12:37	👥 Trackwise Workers
🔗 TrackWise Change Control	06/23/2025 14:36	In Work	06/23/2025 14:37	👥 Trackwise Workers
🔗 TrackWise Change Control Attribute	06/23/2025 12:39	In Work	06/23/2025 12:39	👥 Trackwise Workers
🔗 TrackWise Complaint	06/23/2025 14:47	In Work	06/23/2025 14:47	👥 Trackwise Workers
🔗 TrackWise Correction	06/23/2025 14:56	In Work	06/23/2025 14:57	👥 Trackwise Workers
🔗 TrackWise Correction Attribute	06/23/2025 12:41	In Work	06/23/2025 12:41	👥 Trackwise Workers
🔗 Trackwise Meeting Minutes	06/23/2025 15:21	In Work	06/23/2025 15:21	👥 Trackwise Workers
🔗 TrackWise Object	06/26/2025 10:13	In Work	06/26/2025 10:13	👥 Trackwise Workers
🔗 TrackWise Product Escalation	06/23/2025 15:24	In Work	06/23/2025 15:24	👥 Trackwise Workers
🔗 TrackWise Product Escalation Attribute	06/23/2025 14:06	In Work	06/23/2025 14:07	👥 Trackwise Workers
🔗 TrackWise Quality Event	06/23/2025 15:26	In Work	06/23/2025 15:26	👥 Trackwise Workers
🔗 TrackWise Quality Event Attribute	06/23/2025 14:08	In Work	06/23/2025 14:08	👥 Trackwise Workers
🔗 TrackWise View Data	06/26/2025 10:14	In Work	06/26/2025 10:14	👥 Trackwise Workers
- 👥 truVAULT Workers	06/23/2025 11:51	In Work	06/23/2025 11:51	🏠 IM 360 1.0

Each with as many "skills" as needed.

With Skill inheritance and polymorphism

Each available as primary flows or MCP invoked sub-flows or Tools.



Type Experts + ↺ ↻ ⌵
 Name
 LOC
 - GRAInsight Workers
 - GRAInsight View Data
 - XD GRAInsight Regulatory LOC Product

3 items 1 selected

Digital Workers Projects - Drug Development Process (DDP)
XD GRAInsight Regulatory LOC Product State: In Work, Version: 0.1.1 - Checked Out to ⋮
 Résumé & Properties ● Commands Offered + AI/ETL Skills Available ≡ Helper Definitions ⌵ Responsibilities

Standardize SKU Value State: , Version: 0.1.1 - Checked Out to ⋮
 Properties ⌵ ETL Workflow ⌵ AI/Agentic Workflow ⌵ ETL Execution History

Skill(s)
 + Demo
 + Standardize SKU Value

n8n +
 Home ⌵
 Profile ⌵
 Settings ⌵

Share your workflows with 40k+ users, unlock perks, and shine as a featured template creator!
 Become a creator

Variables ⌵
 Insights ⌵
 Help ⌵
 GlobalQ Inc ⋮

2 items 1 selected

Editor Executions
 Inactive ⏻ Share Saved ↺ ⋮

When clicking "Test workflow" → Destination Market Field → 1. Normalize SAP Product Description Field → 2. Load SAP Embeddings → 3. SKU Matching → Postgres → Respond to Webhook

SKU Matching Workflow Overview
 The SKU Matching Workflow outlines the steps involved in processing and matching SKUs effectively using advanced techniques.
Steps
 1. Accept Optional Input
 2. Field Extraction
 3. Generate and Store Embeddings
 4. SKU Matching

Execute workflow from Webhook1 ⌵

Logs

And responsibilities.

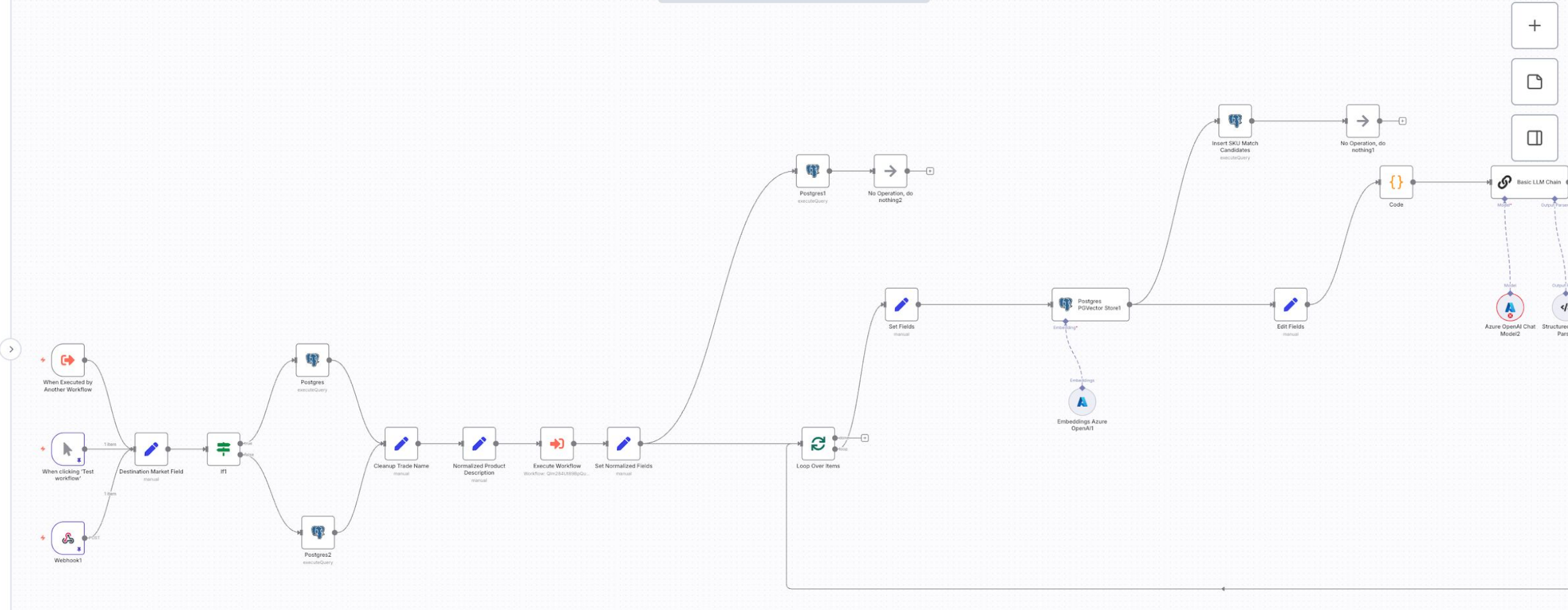
Type Experts
Name
LOC
GRAInsight Workers
GRAInsight View Data

XD GRAInsight Regulatory LOC Product State: In Work, Version: 0.1.1 - Checked Out to
Résumé & Properties Commands Offered AI/ETL Skills Available Helper Definitions Responsibilities
Standardize SKU Value State: ., Version: 0.1.1 - Checked Out to
Skill(s) Properties ETL Workflow AI/Agentic Workflow ETL Execution History

Personal / Product Mapper::SKU Matching + Add tag

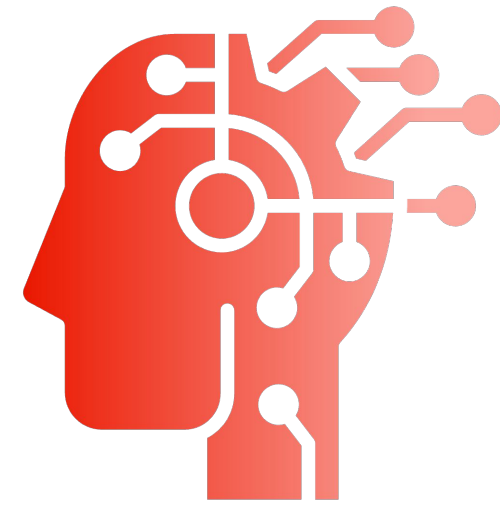
0 / 2 Active Share Saved

Editor Executions Evaluations





What are the results?





DARATUMUNAS

Content Home Action Items Notes Roles History Admin

Documents Regulatory Affairs Post Market Quality Management Laboratory Information Manufacturing Risk Documents

CTD/Submission Records Products Applications Registrations Package Sets CTA-IND Events BLA-NDA Events

CTD Triangle Alias Rule All

Module 1 - Reg. & Admin. Info Module 2 - Summaries & Overviews Module 3 - Quality Module 4 - Non-Clinical Study Reports Module 5 - Clinical Study Reports Non-Module Specific



Regulatory CDT Data for any given Product

Module 5

EDMS Number	Artifact Name	File Type	Compound Asset	CTD Section	eCTD Leaf Title	Country/Region	Group	Sub-Group	Generic Name	Trade Name
> EC045-RM-1459480	Protocol	Word14	JLU-54757414		54757414-0000000000 Protocol		Clinical Study Design	Protocol		
> EC045-RM-85156263	Protocol Elements Document	Word	JLU-54757414				Clinical Study Design	Protocol	Benluminal	
> EC045-RM-85156264	Protocol Elements Document	Word15	JLU-54757414				Clinical Study Design	Protocol	Benluminal	
> EC045-RM-85156175	Protocol Elements Document	Word15	JLU-54757414				Clinical Study Design	Protocol	Benluminal	
> EC045-RM-85156176	Protocol Elements Document	Word15	JLU-54757414				Clinical Study Design	Protocol	Benluminal	
> EC045-RM-758213	Statistical Analysis Plan for a Study	Word14	JLU-54757414		Documentation of Statistical M...		Clinical Study Design	Investigational Plan		
> EC045-RM-1455233	Summary of Clinical Efficacy	pdf	JLU-54757414		Summary of Clinical Efficacy		Clinical Summaries	Clinical Summaries		
> EC045-RM-1455250	Clinical Study Report	pdf	JLU-54757414		CSR Full 54757414-000012014		Other Study Reports	Clinical Study Report		
> EC045-RM-1455280	Integrated Summary of Immunogenicity	pdf	JLU-54757414		Integrated Summary of Immun...		Efficacy and Safety	Reports of Efficacy and Safety...		
> EC045-RM-1455344	Submission Anonymization Report	pdf	JLU-54757414		Submission Anonymization Re...		Clinical Summaries	Clinical Summaries		
> EC045-RM-1455227	Clinical Overview	pdf	JLU-54757414		Clinical Overview		Clinical Summaries	Clinical Summaries		
> EC045-RM-1455244	Population PK Reports	pdf	JLU-54757414		Population PK Reports		Human Pharmacokinetics (PK)...	Reports of Human Pharmacok...		
> EC045-RM-1455254	Clinical Study Report	pdf	JLU-54757414		Documentation of Statistical M...		Other Study Reports	Clinical Study Report		
> EC045-RM-1455246	Summary of Clinical Safety	pdf	JLU-54757414		Summary of Clinical Safety		Clinical Summaries	Clinical Summaries		
> EC045-RM-1455246	Summary of Clinical Safety	pdf	JLU-54757414		Summary of Clinical Safety		Clinical Summaries	Clinical Summaries		
> EC045-RM-1455251	Clinical Study Report	pdf	JLU-54757414		CSR Abbv 54757414-000012014		Other Study Reports	Clinical Study Report		
> EC045-RM-1455252	CSR-ETI Protocol and Amendments	pdf	JLU-54757414		Protocol and Amendments 54...		Other Study Reports	Clinical Study Report		
> EC045-RM-132629735	Clinical Study Report	Word15/Book	JLU-54757414		Appendix (Unspecified) Not Tr...		Other Study Reports	Clinical Study Report	Benluminal	
> EC045-RM-144245241	Protocol	Word15	JLU-54757414		Not Trial Specific 3 Protocol		Clinical Study Design	Protocol	Benluminal	
> EC045-RM-144177431	Protocol	pdf	JLU-54757414		Not Trial Specific 3 Protocol		Clinical Study Design	Protocol	Benluminal	
> EC045-RM-151919432	Protocol	Word15	JLU-54757414		Not Trial Specific 3 Protocol		Clinical Study Design	Protocol	Benluminal	
> EC045-RM-1455253	Integrated Summary of Immunogenicity	pdf	JLU-54757414		Integrated Summary of Immun...		Efficacy and Safety	Reports of Efficacy and Safety...		
> EC045-RM-200440372	Clinical Study Report	Word15	JLU-54757414		Synopsis 54757414-000012000		Other Study Reports	Clinical Study Report		
> EC045-RM-200148030	Analytical Methods and Validation Report (C-PC)	Word15	JLU-54757414		PKA-AL-005-1054 Validation...		Analytical Methods and Valid...	Analytical Methods and Valid...		
> EC045-RM-200148010	Clinical Study Report	Word15	JLU-54757414		Study Report 54757414-000012...		Other Study Reports	Clinical Study Report		
> EC045-RM-200440370	Clinical Summary Reference List	Word15	JLU-54757414		Clin Sum Ref List		Clinical Summaries	Clinical Summaries		
> EC045-RM-1455263	Clinical Study Report	pdf	JLU-54757414		CSR Full 54757414-000012004		Other Study Reports	Clinical Study Report		
> EC045-RM-1455246	Summary of Clinical Safety	pdf	JLU-54757414		Summary of Clinical Safety		Clinical Summaries	Clinical Summaries		

107 items

Data Current as of: 09/13/2025



Product Product Families Products Large Molecules Small Molecules

Manufacturing Batches

DARATUMUMAS

Content Home Action Items Notes Roles History Admin

Documents Regulatory Affairs Post Market Quality Management Laboratory Information Manufacturing Risk Documents

Materials Batches Batch Flows SC Maps

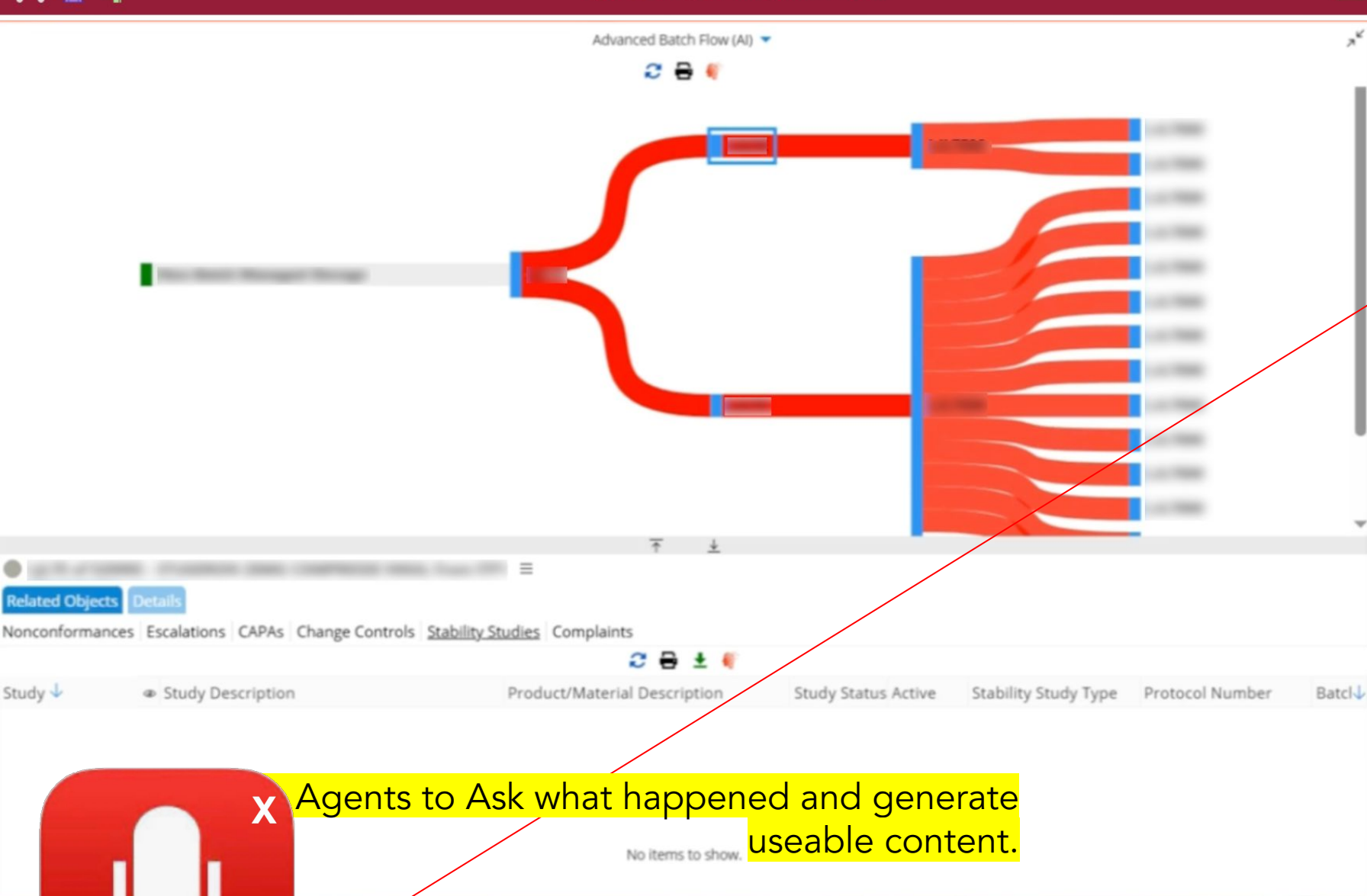
Filtered Alias Rule All

Default APR/PQR (Non GxP) Standard

O/P Batch Code	O/P Localized Batch Code	O/P Vendor Batch No.	O/P Product Code	O/P Process Order	O/P Product Code Description	O/P International Brand	O/P Product Type	O/P Disposition Status	O/P Plant Code	O/P Plant Name	O/P Source
QF000	QF000		444004	20074700	DARA SC COMM 120MG/ML SOLUTION...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
Q005A	Q005A		444074	20002140	DARA SC COMM 120MG/ML SOLUTION...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
Q401E	Q401E		444396	20074600	DARDALEX 20MG/ML SOLUTION SA	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
LB0000	LB0000		415422	20767907	DARDALEX 1X100MG VAL PORT SPAIN	DARDALEX	Finished Good	Approved	CHP2	MFG Schaffhausen	EU2
Q010Z	Q010Z		444704	20000000	DARA SC COMM 120MG/ML SOLUTION...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
PA010	PA010		444396	20013270	DARDALEX 20MG/ML SOLUTION SA	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
M01U	M01U		444004	20040070	DARA SC COMM 120MG/ML SOLUTIO...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
KE00R	KE00R		444000	20720000	DARA SC COMM 120MG/ML SOLUTIO...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
MC00L	MC00L		444000	20024000	DARA SC COMM 120MG/ML SOLUTIO...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
AA000	AA000	81F000001		20000000	DARDALEX SC COMPOUNDING	DARDALEX	Sub	Approved	SE21	MFG Schaffhausen	PCA
MF02Y	MF02Y		444000	20007000	DARA SC COMM 120MG/ML SOLUTION...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
NA01F	NA01F		444074	20000010	DARA SC COMM 120MG/ML SOLUTION...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
ZIC10	ZIC10		307771	077001	DARDALEX UNLABELED VAL 00MG 2...	DARDALEX	Final Sub		NA17	EM US	STN
ND00F	ND00F		444396	20000004	DARDALEX 20MG/ML SOLUTION SA	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
L000	L000		444000	20000004	DARDALEX 20MG/ML SOLUTION H1P7	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
M000H	M000H		444000	20000020	DARDALEX 20MG/ML SOLUTION H1P7	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
PL000	PL000		444074	20002000	DARA SC COMM 120MG/ML SOLUTION...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
KH01K	KH01K		444396	20700001	DARDALEX 20MG/ML SOLUTION SA	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
Q000U	Q000U		444704	20070000	DARA SC COMM 120MG/ML SOLUTION...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
AA0001A	AA0001A	81F000000		00000000	DARDALEX PASPRO 1X100MG VAL 0...	DARDALEX	Finished Good	Approved	SE21	MFG Schaffhausen	PCA
NC000	NC000		444000	20070000	DARA SC COMM 120MG/ML SOLUTION...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
PE0000M	PE0000M		407470	20040007	DARDALEX 1X100MG VAL 00F	DARDALEX	Finished Good	Approved	CHP2	MFG Schaffhausen	EU2
LB10	LB10		444000	20002000	DARDALEX 20MG/ML SOLUTION H1P7	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
LC010	LC010		444396	20700000	DARDALEX 20MG/ML SOLUTION SA	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
LAS0H	LAS0H		444396	20717004	DARDALEX 20MG/ML SOLUTION SA	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2
QH02U	QH02U		444704	20002000	DARA SC COMM 120MG/ML SOLUTION...	DARDALEX	Sub	Approved	CHP2	MFG Schaffhausen	EU2

150+ items 1 selected

Data Current as of: 09/13/2025



Hi [redacted], I see you're looking at POC Batch Advanced - Batch Flow Selector. How can I help?

can you please summarise all of the non conformances with this flow

summarize all of the non conformances with this flow

Summary of All Non-Conformances in This Flow

Below is a summary of all non-conformances identified for the batch flow associated with [redacted] sourced from [redacted]

Batch ID	Event Title	Impact Level	Root Cause	Impact Summz
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

IM360 Ask! Ask me anything! (press and hold ALT key for dictation)



Agents to Ask what happened and generate useable content.

summarize all of the non conformances with this flow



Product Families

Content Home Action Items Notes Roles History Admin IntelliWriter

Documents Regulatory Affairs Post Market Quality Management Laboratory Information Manufacturing Risk

Change Controls Escalations Nonconformances CAPAs Audits Accounts by User

Nonconformances Containments NC Investigations Supplemental Investigations Laboratory Investigations NC Correction

COMET Filtered Alias Rule All

Home User Comments History

Details Related Objects

Immediate Causes NC Investigations Laboratory Investigations CAPAs Actions Change Controls Escalations Batches

Batch Explorer Batch Flow Material Flow Related Objects Release Plan

Nonconformances Escalations CAPAs Change Controls Stability Studies Complaints

Study	Study Description	Product/Material Description	Stuc
			A

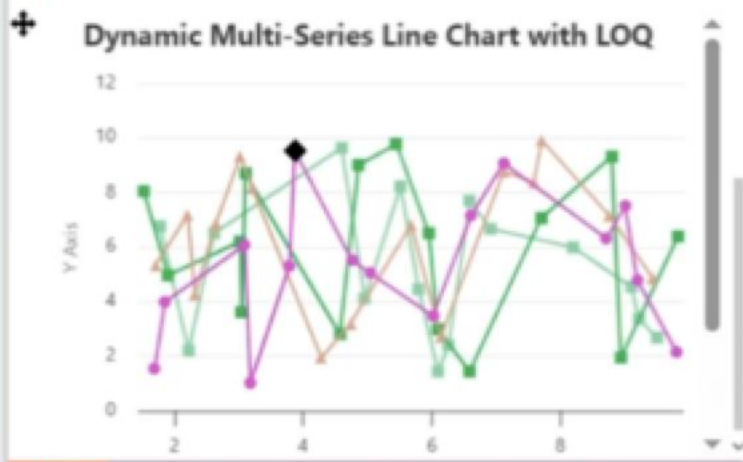
1 item

Summary

The CAPAs implemented and planned aim to address the root cause of the contamination and ensure that similar issues do not occur in the future. Immediate corrective actions, such as inspecting and clearing the drums, were completed, while supplier-related preventive actions are ongoing or planned.

can you give me a scatter plot of all of the results in this stabilities study

Here you go:



Using Agents to Ask what happened and generate useable content.



can you give me a scatter plot of all of the results in this stabilities study

IM360 Ask!





Ideally, unstructured content is just as accessible.

Module 1

Content Home Action Items Notes Roles History Admin

Documents Regulatory Affairs Post Market Quality Management Laboratory Information Manufacturing Risk Documents

CTD/Submission Records Products Applications Registrations Package Sets CTA-IND Events BLA-NDA Events

CTD Triangle Alias Rule All

Module 1 - Reg. & Admin. Info Module 2 - Summaries & Overviews Module 3 - Quality Module 4 - Non-Clinical Study Reports Module 5 - Clinical Study Reports Non-Module Specific

EDMS Number	Artifact Name	File Type	Compound Asset	CTD Section	eCTD Leaf Title	Country/Region	Group	Sub-Group	Generic Name	Trade Name
EU-1537381	Review Unit	pdf	JLU-04757414	N.A.			Administrative	General		
	Dara SC Samsung PAS 3.2 Body of Data - EU-1537381									

Dara SC Samsung PAS 3.2 Body of Data - EU-1537381.pdf

File Details

Download Print Refresh

1.2 Background to the Variation

INTRODUCTION

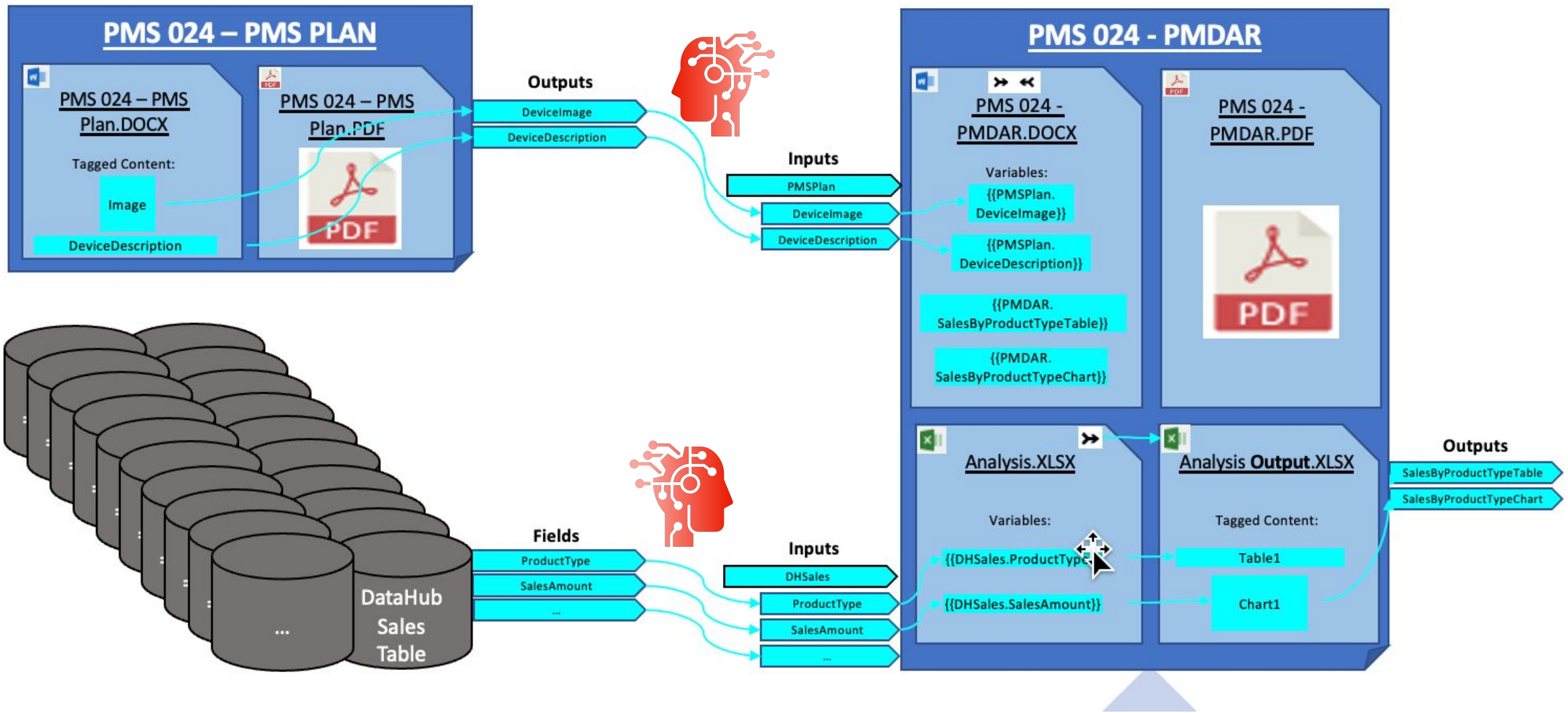
Samung Cilag International N.V. (the MAH) is submitting a Single Type II variation for Dexamethasone (Dexamethasone), concentrate for solution for infusion and solution for injection.

The Type II variation concerns changes to the Dexamethasone, concentrate for solution for injection (DSC).

EU-1472743	Response to Questions	pdf	JLU-04407504	SI	Quality Response to Health A.	GLD	Administrative	General	Regulatory	EU-1472743
EU-1375721	Certification Declaration Letters Statements	pdf	JLU-0407507	N.A.	Statements	GLD TR	Administrative	General	Regulatory	EU-1375721



“Data & Records create a Knowledge Network.”





External Data Streams

- Cortellis Reg Intelligence
- Cortellis HTA Intelligence
- PV & Drug Safety
- OFF-X
- BioWorld
- MedTech 360
- Market Intelligence Data
- DRG Policy Tracker
- Cortellis Drug Discovery
- Epidemiology
- Cortellis Competitive Intel
- Patient Journey
- Web of Science
- Real World Data
- Drug Safety Triager
- Med Lit Monitoring
- Dialog

Content



- R/A
- R&D
- Clinical
- Sales
- Post Market

INTELLIGENT DOCS TRAINED TO WRITE THEMSELVES

Internal Data Streams



- Clinical Evaluation Report
- Clinical Evaluation Plan
- Clinical Activity Report
- PMCF Plan
- PMCF Report
- Risk Management Report
- SSCP - Summary Safety &
- PSUR - Periodic Safety Update Report
- Any Document
- APPROVED



File Home Insert Draw

Times New Roman

B I U A

Headings

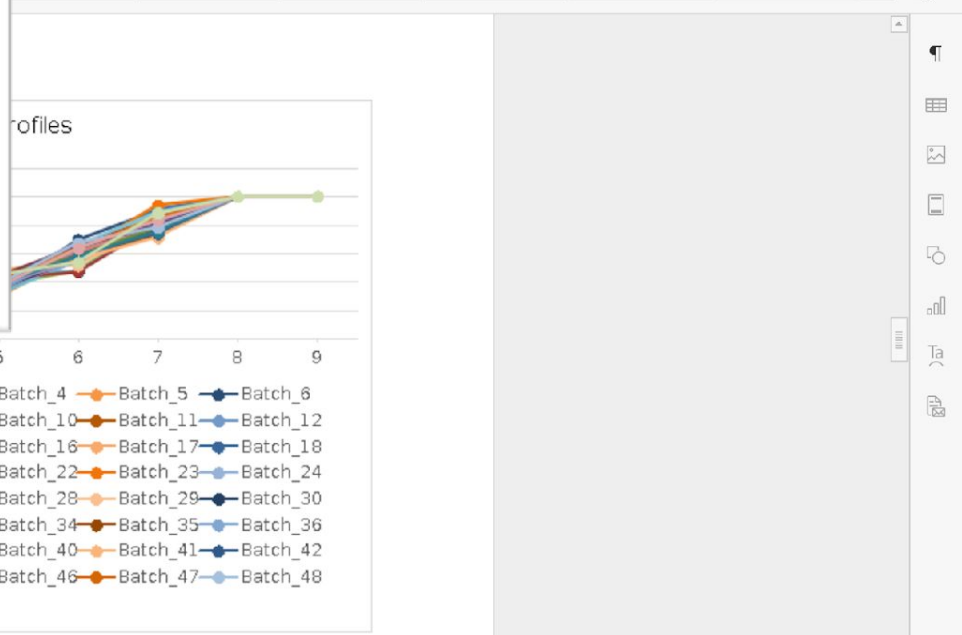
- manufacturer]
- 2.3.S.4 Control of Drug Substance [name, manufacturer]
- 2.3.S.5 Reference Standards Materials [name, manufacturer]
- 2.3.S.6 Container Closure System [name, manufacturer]
- 2.3.S.7 Stability [name, manufacturer]
- 2.3.P DRUG PRODUCT [NAME, DOSAGE FORM]
 - 2.3.P.1 Description and Composition of the Drug Product
 - 2.3.P.2 Pharmaceutical Development [name, dosage form]
 - 2.3.P.2.1 Components of the Product
 - 2.3.P.2.1.1 Drug Substance
 - 2.3.P.2.1.2 Excipients
 - 2.3.P.2.2 Drug Product
 - 2.3.P.2.3 Manufacturing Process Development (This section is optional for a non critical dose drug formulated in a solution or an immediate release dosage form)
 - 2.3.P.2.4 Container Closure System
 - 2.3.P.3 Manufacture [name, dosage form]
 - 2.3.P.4 Control of Excipients [name, dosage form]
 - 2.3.P.5 Control of Drug Product [name, dosage form]

Activities

- Stage 2: Ph 1/2 Mfg Readiness
 - Activity Not Started
- Stage 3: FIH Readiness
 - Activity Not Started
- Stage 4: PH IIb/III Dev. Plan
 - Activity Not Started
- Stage 5: Entry into Full Dev.
 - TPP-CMC Lock Not Started
 - API & DP Source Lock Not Started

Editing

Heading 9 | Heading 1 | Heading 2 | Heading 3 | Heading 4 | Heading 5



compared to the complexities involved in developing a single multilayered IR and CR pellet in Prototype II.

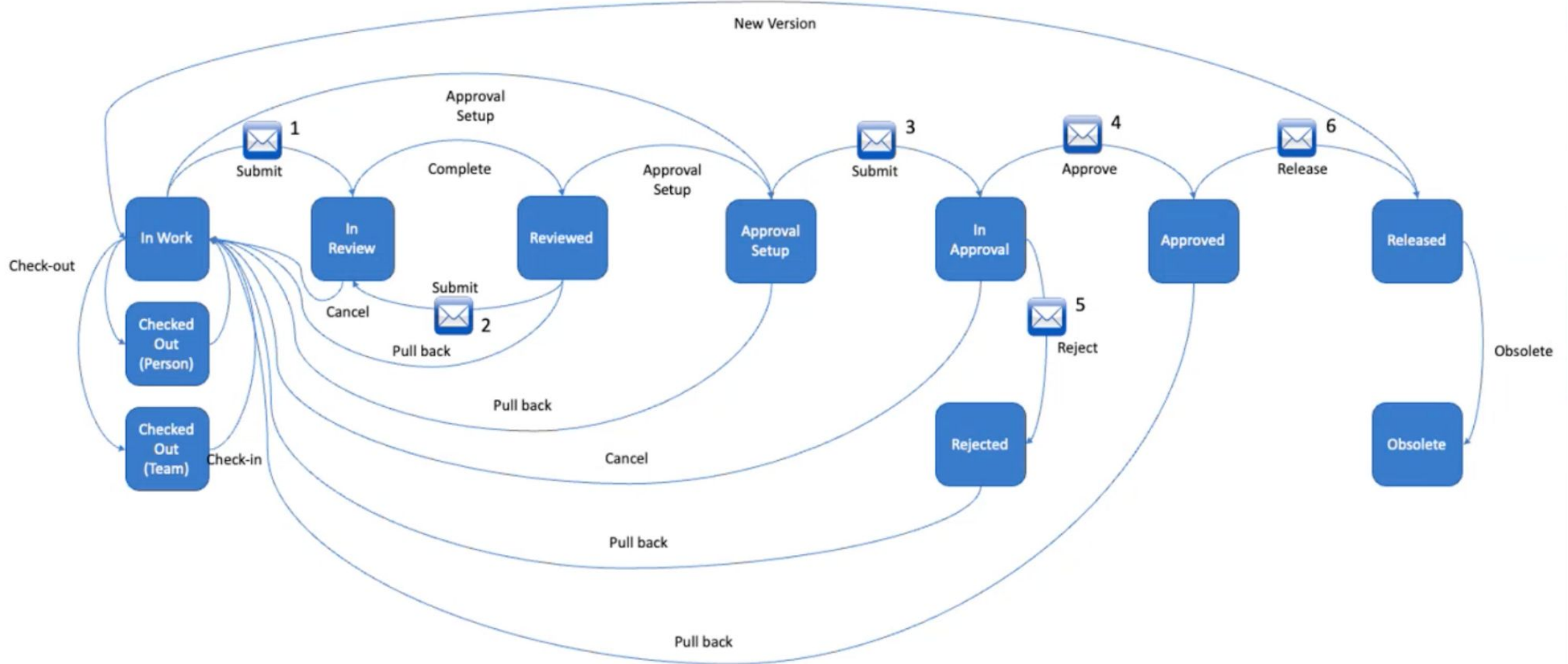
For full details regarding dosage form design, please refer to Module 3.2.P.2.2.1.

How were the excipients and their grades selected?

Excipient Selection:

Clear coating 732 (comprised of hypromellose and polyethylene glycol) was chosen as a binder to help the LR-12345 drug adhere to the sugar spheres. Ethylcellulose (hydrophobic polymer) and triethyl acetate (plasticizer) were chosen as components of the rate controlling membrane. These choices were based upon prior experience with the above excipients in an analogous approved product (e.g. IT ER Capsules (ANDA [www](#))) and upon the observed compatibility of these excipients with LR-12345 (refer to Module 2.3.P.2.1.2).

“Data & Records create a Knowledge Network.”



Helpful Principles

- Start small...
 - but eventually pick the toughest problems in the room
- Meet people where they are
 - then put their seat belt on and go
- Don't forget your basic algebra
 - $E=MC^2$ still relies on first principles
- Architect Globally
 - deliver locally, or at least make it feel that way
- Don't just impress...
 - operationalize
- Spread the wealth, share the glory
 - federations can flourish, empires can fall

1995 (30 Years Ago)



従来ツール...

Project Management & Workflow (Workflow)

CAD

Cost & Resource (Resource) Management

BOM & Inventory Management

MRP

Doc Mgt (Document Management) & Control

E≠MC²

- 現実 (Reality) を反映しない
- 膨大な時間 & 円
- 表形式 (Tables) は自然ではない
- 業務側の変更 (change) を要求

Knowledge Center™



2017 (8 years ago)

INNOVATION INSIGHTS AND GUIDED COMPLIANCE



INNOVATION INSIGHTS AND GUIDED COMPLIANCE Share

COGNITION

GENER

HOW DO THEY EVOLVE?

Needs: Meeting Minutes, Interview Guides, Electronic Affidavit Programming (KJ)

Requirements: Concept Selection, Pugh, Benchmarking, Voting, Attachments, Electronic Notebooks, GFD, etc.

Validation Tests: Automatic Status Tracking, Workflow Status & Reporting

Submission: Transfer Function Definition, QoS/PNC Computation, Monte Carlo, DOE, etc.

Albert Einstein: Everything should be made as simple as possible, but not simpler.



Think forward

Mitch Hayes – Senior Vice President and GM
Optiqs360 Digital

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781.858.6878

About Clarivate

Clarivate is a leading global provider of transformative intelligence. We offer enriched data, insights & analytics, workflow solutions and expert services in the areas of Academia & Government, Intellectual Property and Life Sciences & Healthcare. For more information, please visit clarivate.com.

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Advancing Quality & Compliance

HARNESSING GENERATIVE AI TO DIGITIZE YOUR QUALITY MANAGEMENT SYSTEM

John Leamy
Oct 28th 2026

What are we seeking to transform

QMS Workflows - examples



Corrective & Preventive Action



Nonconformance Management



Internal Audit



Change Control



Complaint Processing

Process Activities



Quality Record Creation



Failure Investigation



Bounding & Traceability



Document Writing



Trends & Reports

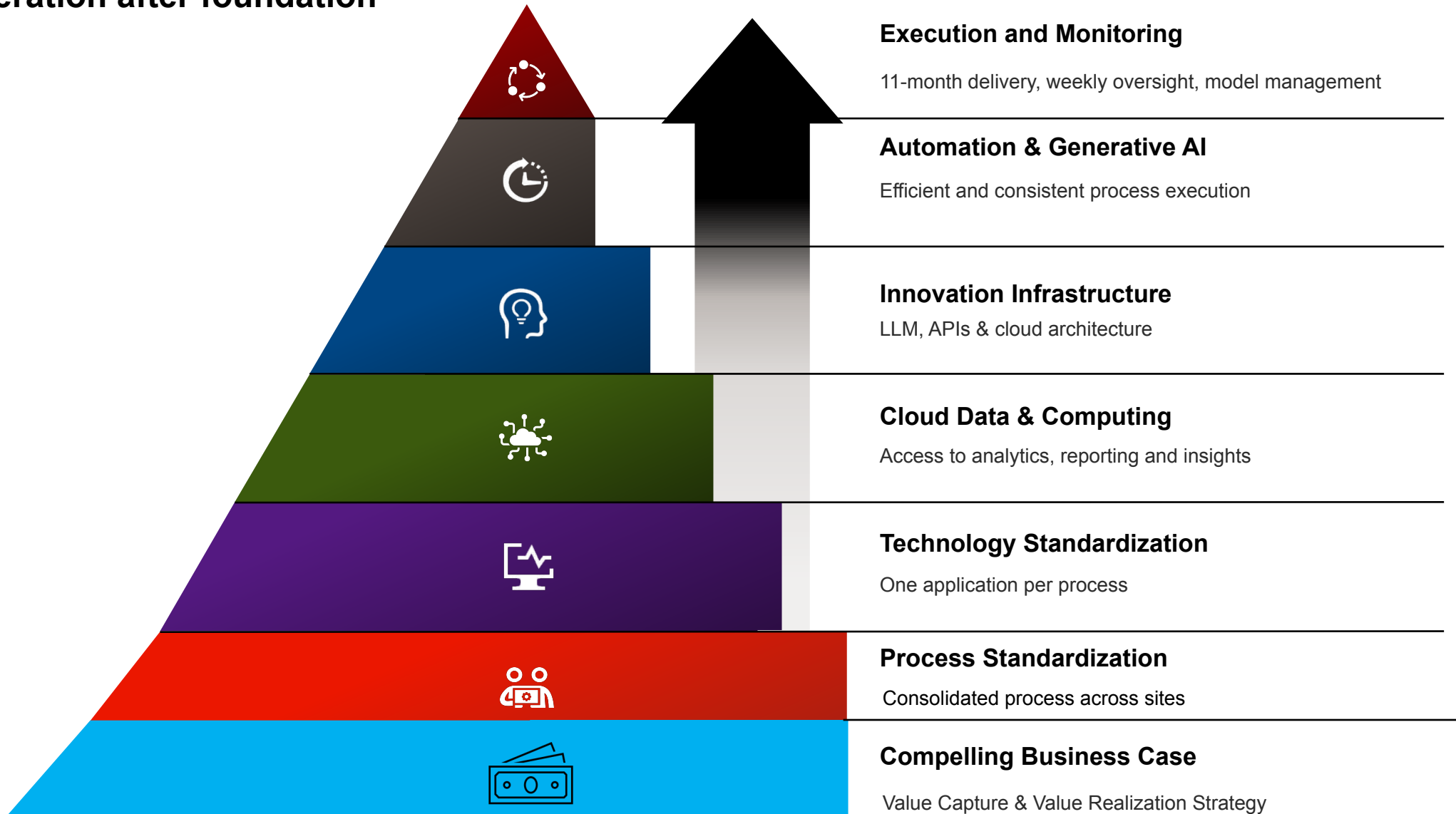


Regulations & Oversight

QMS Digitalization Transformation

Fundamentals

Acceleration after foundation

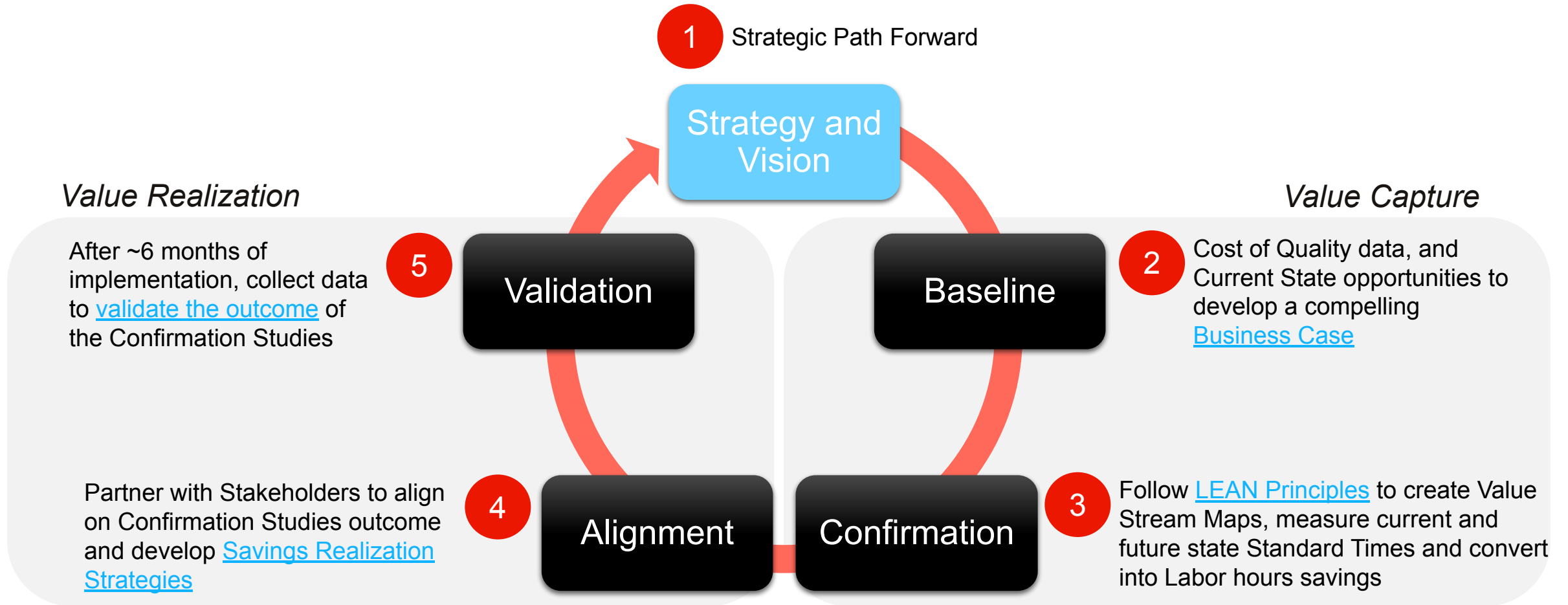


Why

“Productivity is being able to do things that you were never able to do before.”
Franz Kafka

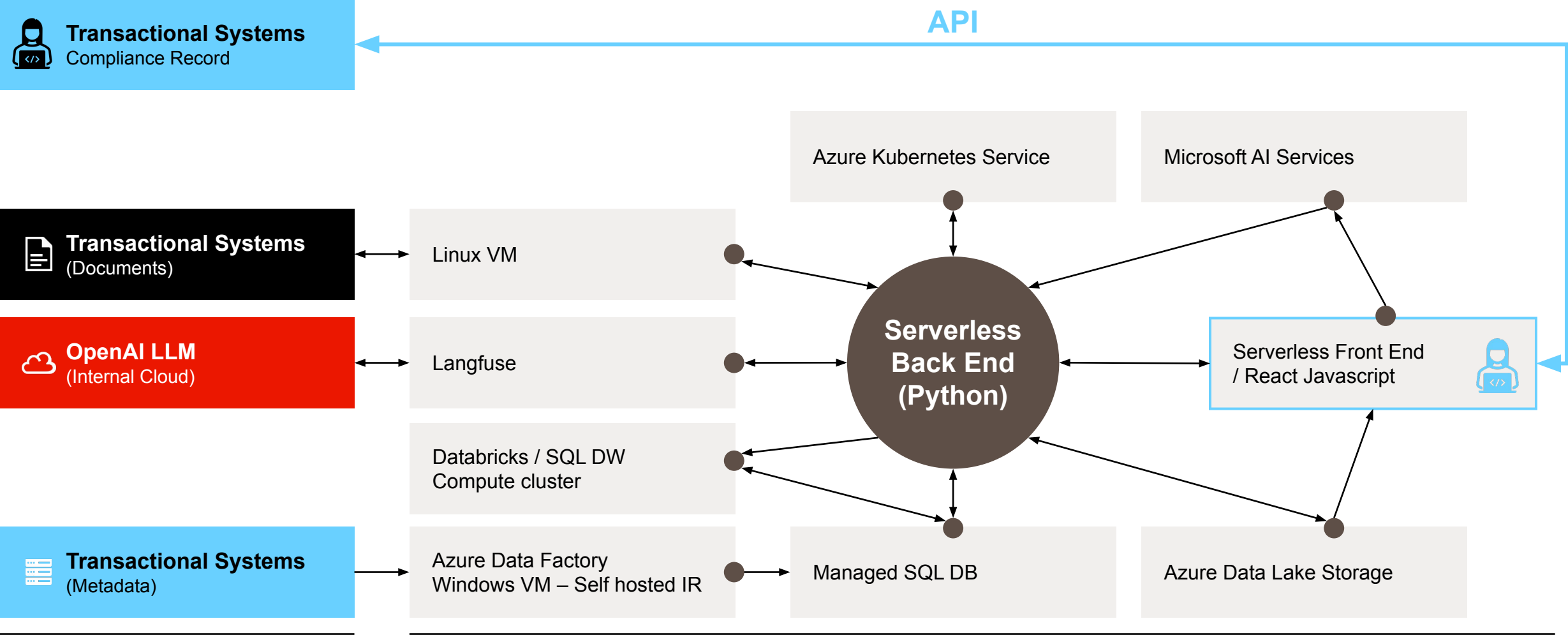
Agile Business Case -Value Framework

Goal: Operationalize Digitized QMS



Digital QMS Infrastructure

High level architecture diagram



Company Intranet

Azure Cloud- VPCx

J&J MedTech

Quality & Compliance

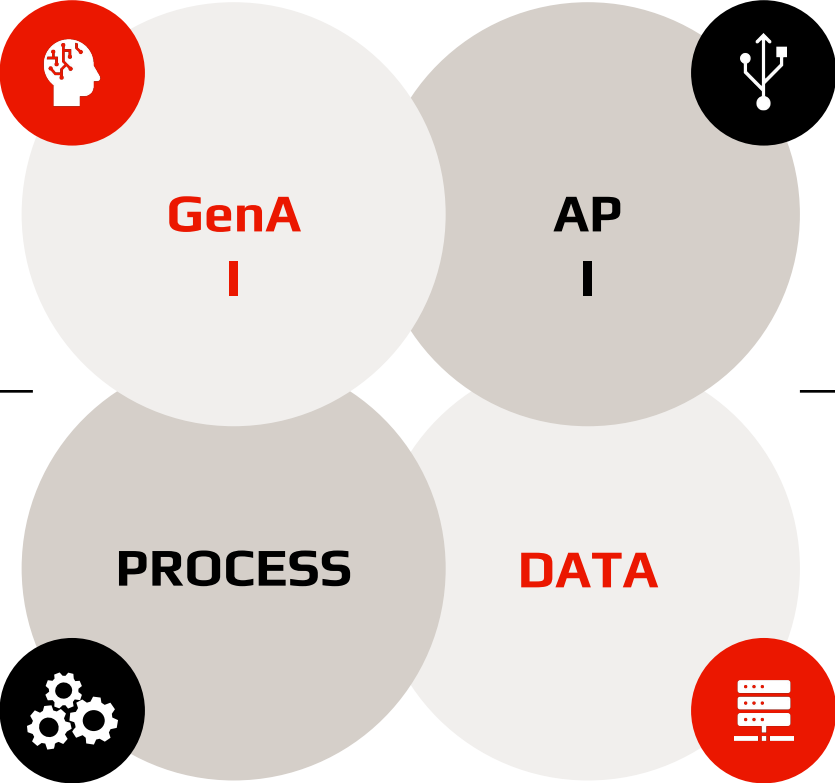
Innovative Approach

Valuing the experts through efficiency

Technology reduces non-value added time and complexity to execute quality and compliance processes

LLM Capabilities

Text generation, entity extraction and process specific prompt -Reduce execution time.



Automated System Entry

Multiple systems and data accessibility add complexity addressed by APIs.

Technology Enabled Compliance

Procedure based UI/UX ensuring all actions complete the first time.

Access & Reports

Requesting data and tracking reports from multiple sources in one interface








Regulatory Compliance & Controls Monitoring

Current Regulatory landscape

Regulation, Standard or Guidance	Region	Type
The EU AI Act ((EU) 2024/1689)	EU	Act
UK (MHRA) Guidance - Software and AI as a medical device	UK	Guidance
U.S. FDA Draft Guidance: AI-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations	U.S.	Draft Guidance
U.S. FDA Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for AI-Enabled Device Software Functions	U.S.	Guidance
U.S. FDA Digital Health and AI Glossary	U.S.	Guidance
ISO/IEC 42001:2023, Information technology — Artificial intelligence — Management system	Global	Standard

LLM/GenAI Metrics, Controls and Monitoring

Generation & Classification

METRICS	Criteria	Coherent 	Relevant 	Grounded  	Concise  	Accurate 
	Focus	Grammar, structure, readability, appropriateness	Aligned to the task and user input	Connected and limited to source data inputs	To the point without embellishment	Most relevant categories, labels and groupings
CONTROLS	Technical	System & User prompts	<ul style="list-style-type: none"> • System & User prompts • Task based user inputs • Internally sourced data 		System & User prompts	<ul style="list-style-type: none"> • System & User prompts • Explanation and rationale
	Process	Human in the loop				
PERFORMANCE	Validation	<ul style="list-style-type: none"> • Quantitative measure baseline established via technology (e.g. accuracy, response time, user satisfaction, usage, user behavior) • Subject matter expert review and approval of LLM / GenAI output 				
	Production	<ul style="list-style-type: none"> • Quantitative monitoring against established baseline via technology (e.g. trend analysis, pattern recognition and anomaly detection) • Standard process monitoring and auditing 				

Generation: Text writing and content creation
(e.g. ChatGPT)



Classification: Grouping and labeling inputs
(e.g. Spam Filter)



Digital QMS

Simplification & Optimization of QMS through Digital Transformation by Citizen Developers

Gartner: 80% of technology solutions will be built by professionals outside of IT by 2024

McKinsey: Organization that empowers citizen developers score 33% higher on Innovation



Citizen Developers – Business & Process Owners, Domain Experts, Functional Leaders

Innovation Success Factors

Collective ownership and iterative progress are critical

Change Management

Grow Digital
Acumen

Change
Agents

Leadership
Engagement

Adoption
Metrics

Project Philosophy

Progress Over Perfection

Product Backlog

Implement at Scale

Project Management

Business & Technology members



Business Representation

Highly technical
business organization
co-developing in some cases

Technology Representation

Business knowledgeable
technology organization with clear
process understanding

Outcomes

What advancing innovation looks like



More time for experts to innovate and improve –
Proactive Quality



Data-based process monitoring



Measures of usage to drive adoption



Validated LLM consistency and ownership



Business ownership of LLM performance



Trust in Technology to improve outputs

