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

Clarivate

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Years of historical content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 universities[1]

100%
Top Pharma, Biotech, Medtech[2]

75%
National & regional research assessments

96%
Top 50 companies by R&D spend[3]

90%
Top 10 brands[4]

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)

Clarivate™

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

28th October 2025

Medical Device Summit 2025

Optimizing Human Potential

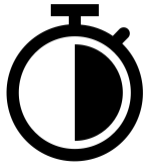
Mitch Hayes, Senior Vice President, General Manager

28th October 2025

My Journey…

3 Companies, 35 Years

30 Years Ago



8 Years Ago

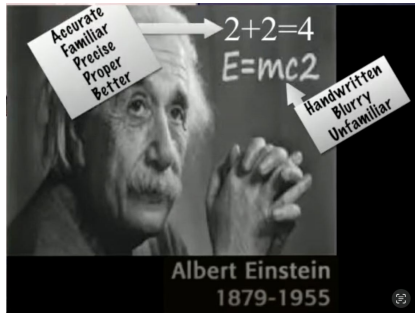
Today

– Same Mission –
Data Visibility and Work Facilitation

My Journey…

Data Visibility and Work Facilitation

Power to See, Understand, & Work



Global Q

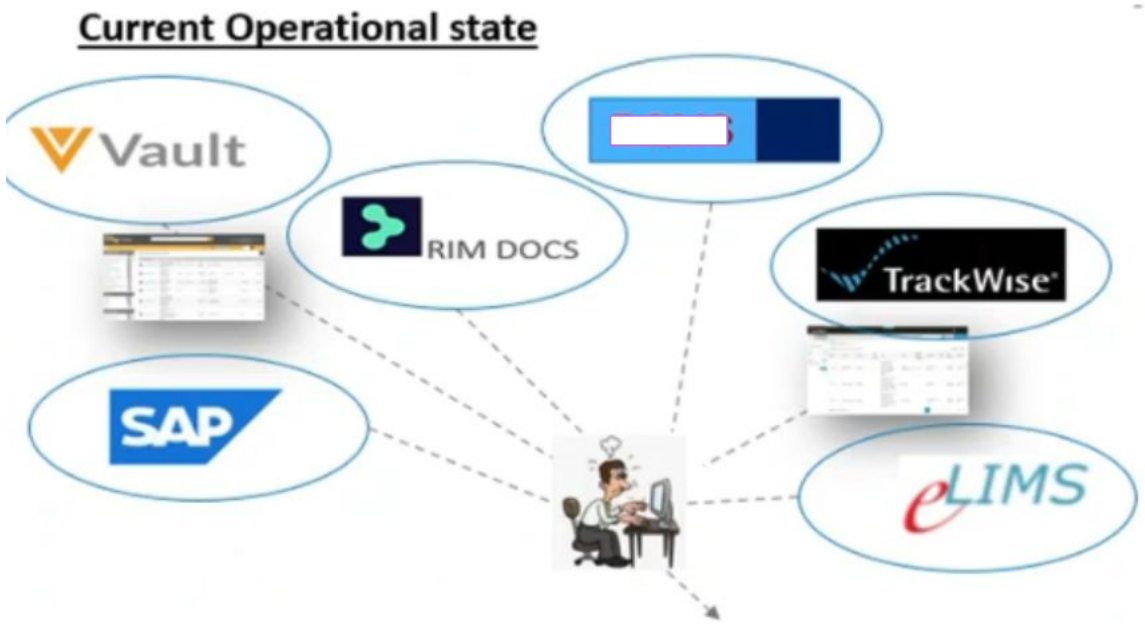
Optiqs 360 Digital™

Clarivate™

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

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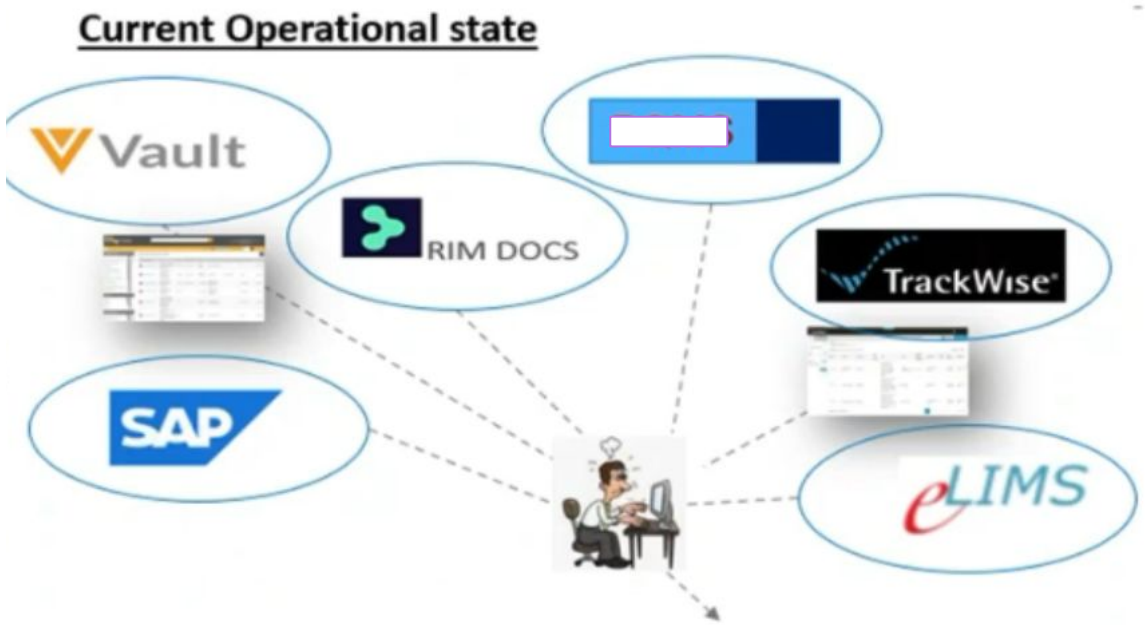
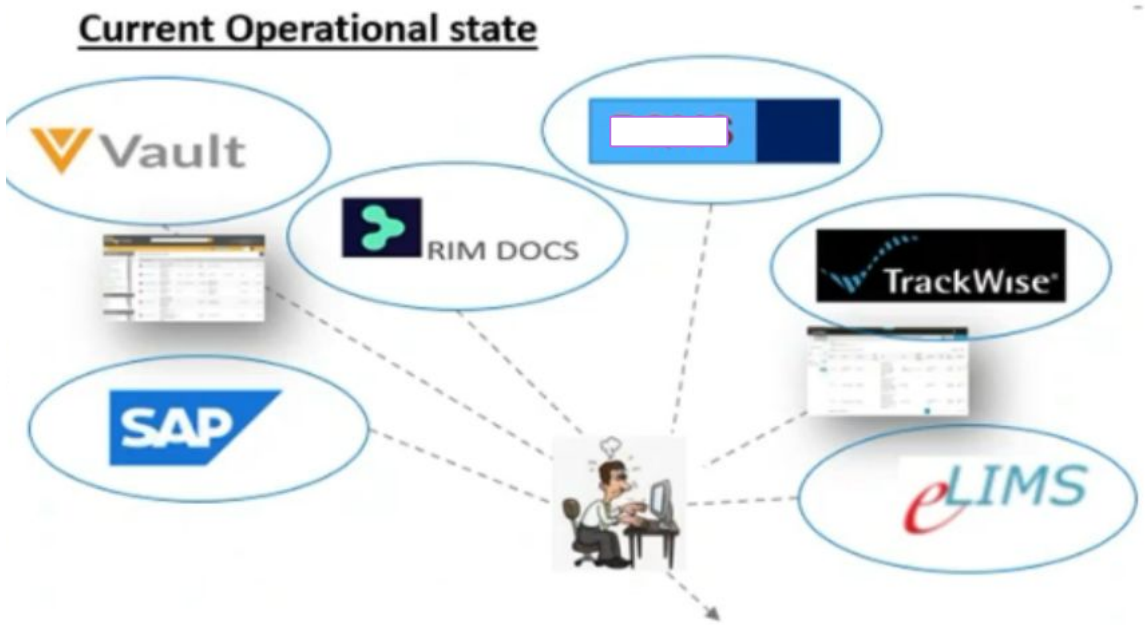


- Manual, Redundant Processes: Teams spend significant time on repetitive tasks like data reconciliation, reporting, and compliance checks, diverting focus from innovation and increasing the risk of human error.

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.

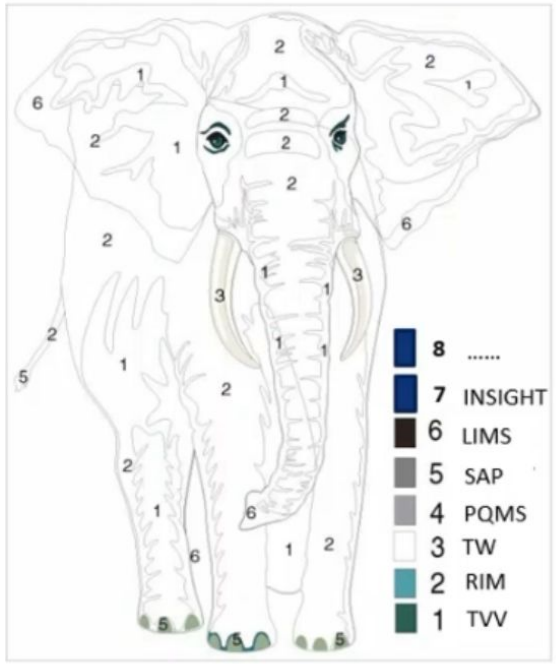
- Compliance and Traceability Risks: Inconsistent data and lack of standardized processes create vulnerabilities in regulatory audits, leading to potential delays, costly remediation, and reputational damage.

Clarivate™

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

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
- Cortellis HTA Intelligence
- PV & Drug Safety
- OFF-X
- BioWorld
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- Market Intelligence Data
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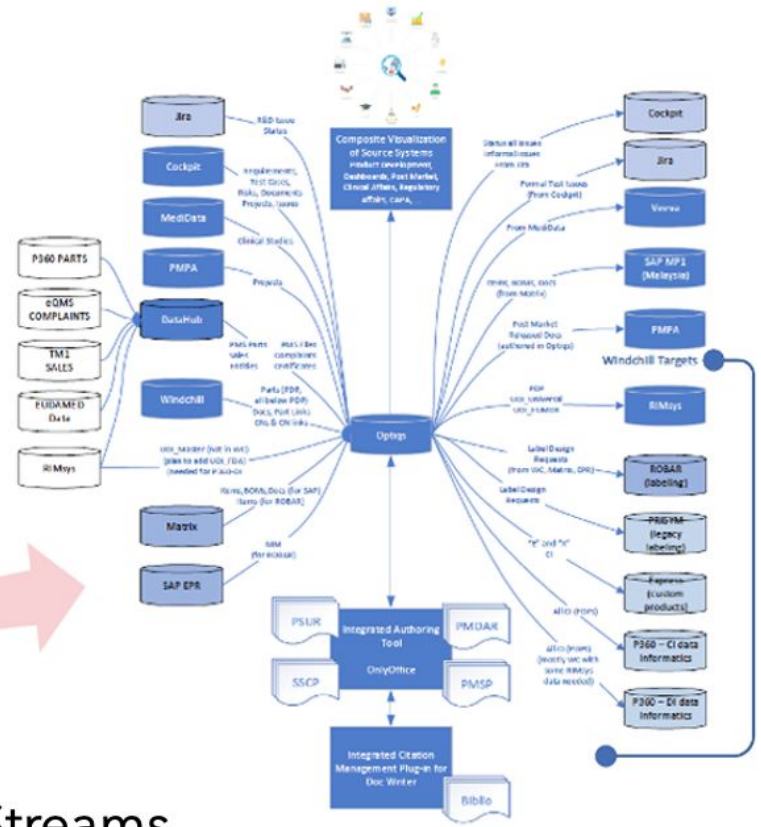

Internal Data Streams

Vision for helping improve conditions

External Data Streams

- Cortellis Reg Intelligence
- Cortellis HTA Intelligence
- PV & Drug Safety
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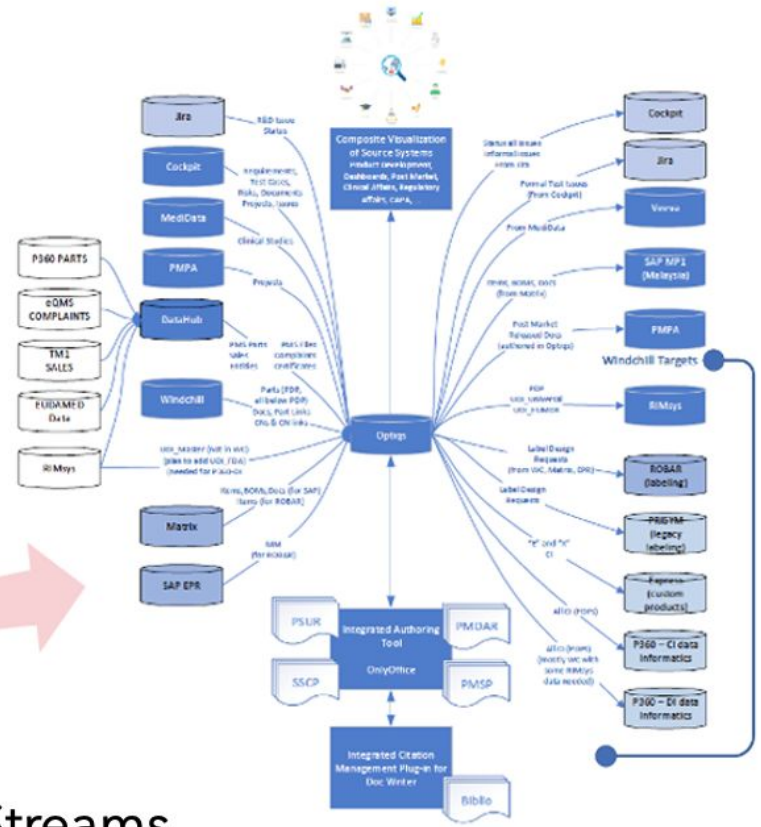
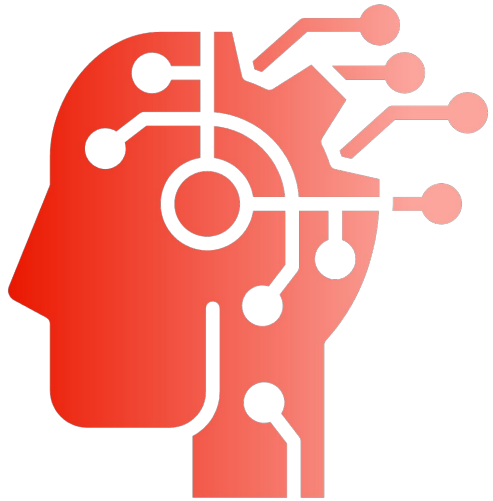
- Dialog





Internal Data Streams

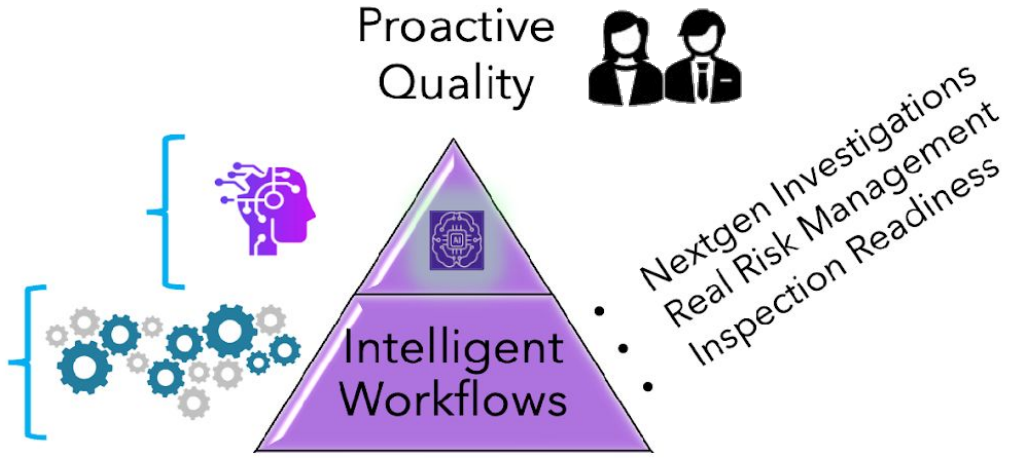
Vision for helping improve conditions

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



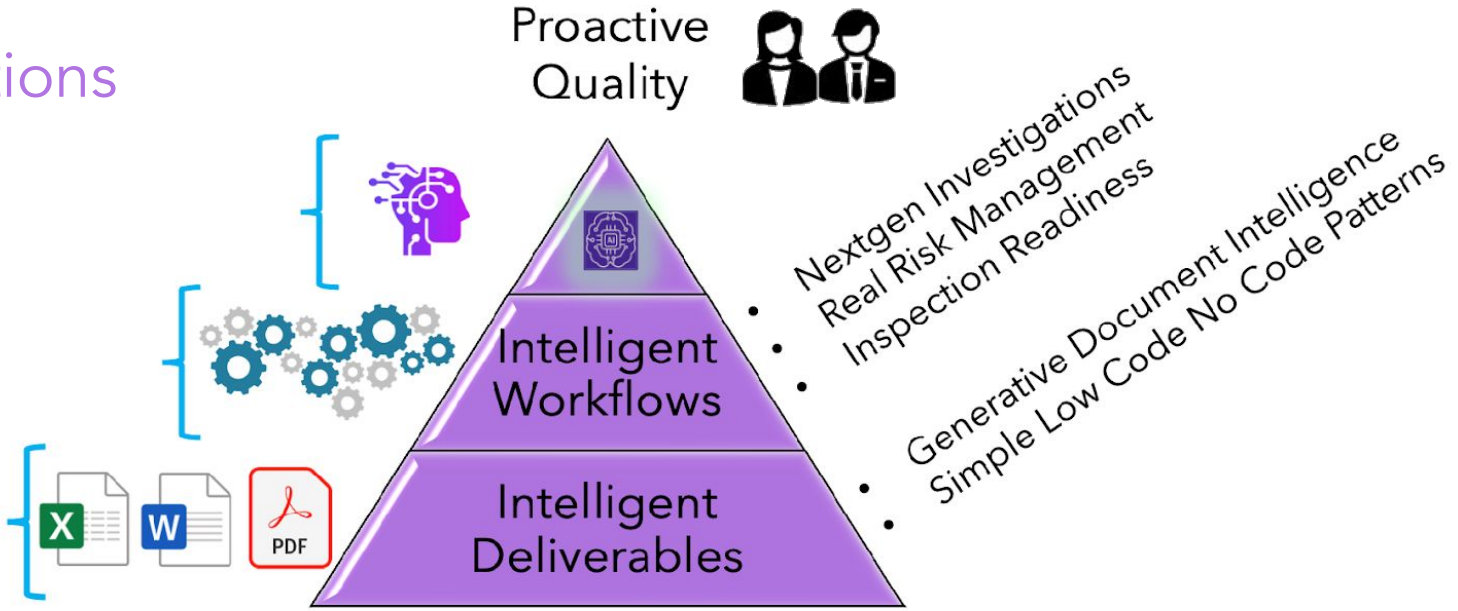
Clarivate™

Vision for helping improve conditions

5. Agents working on Insights, Triggers, & Responses

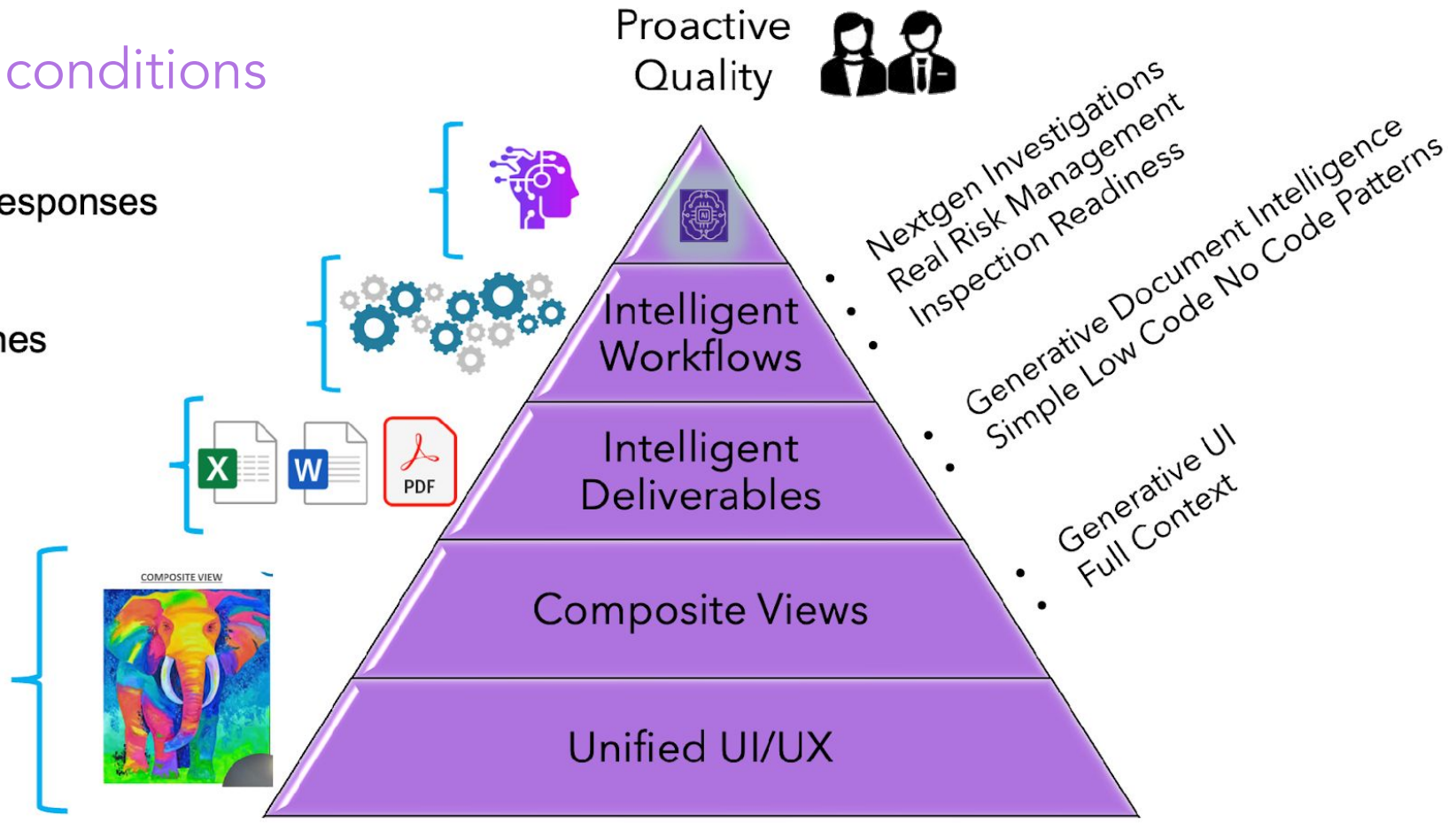
4. Agents working on Work Process/Guidelines

3. Agents working on Deliverables/Artifacts



Vision for helping improve conditions

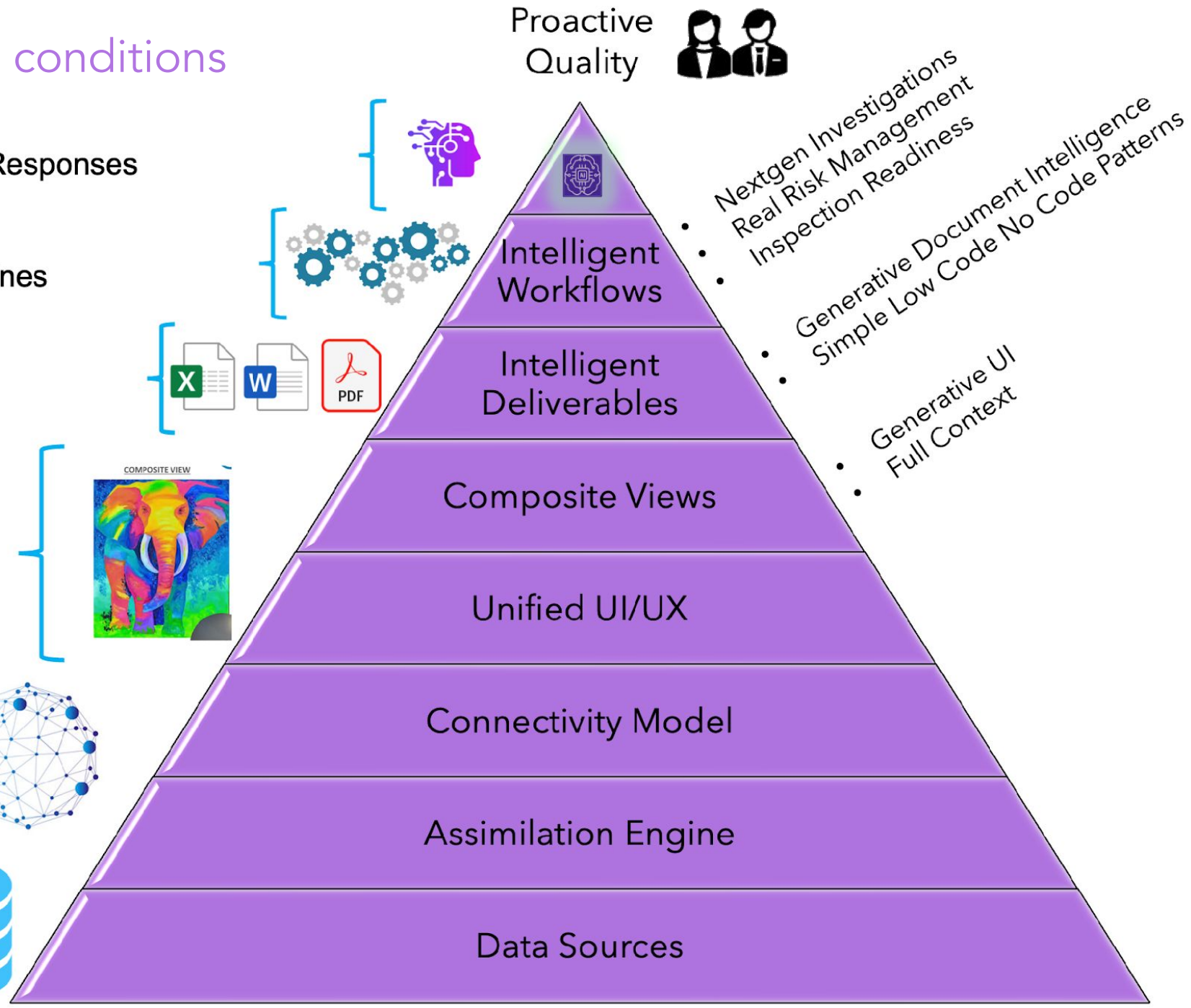
5. Agents working on Insights, Triggers, & Responses
4. Agents working on Work Process/Guidelines
3. Agents working on Deliverables/Artifacts
2. Agents working on Composite UI/UX



Clarivate™

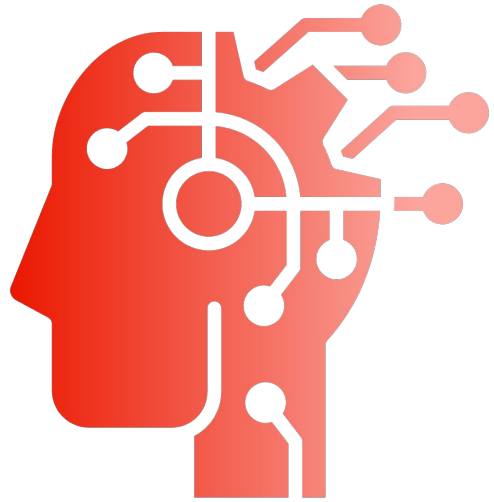
Vision for helping improve conditions

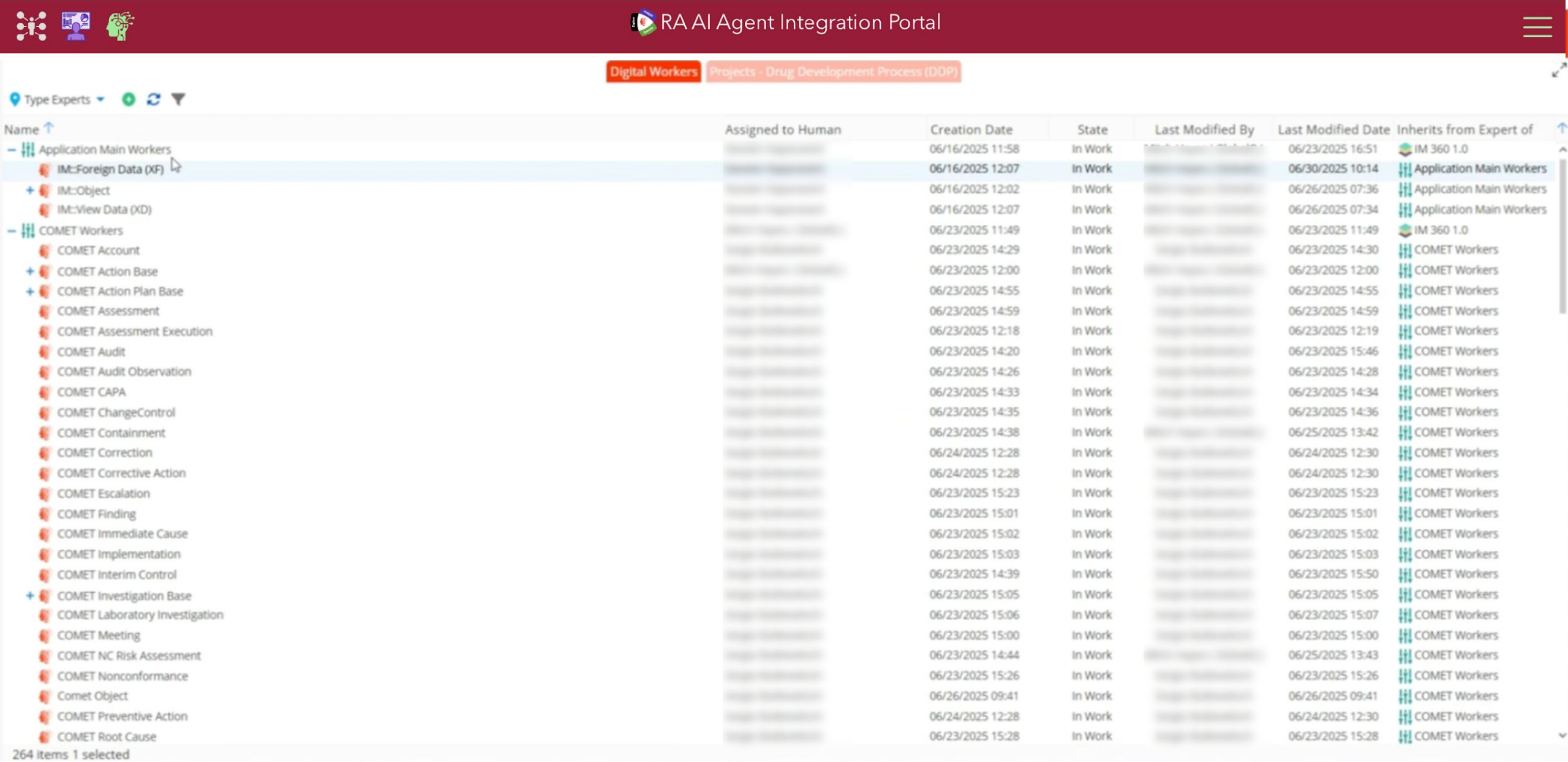
5. Agents working on Insights, Triggers, & Responses
4. Agents working on Work Process/Guidelines
3. Agents working on Deliverables/Artifacts
2. Agents working on Composite UI/UX
1. Agents working on the Data



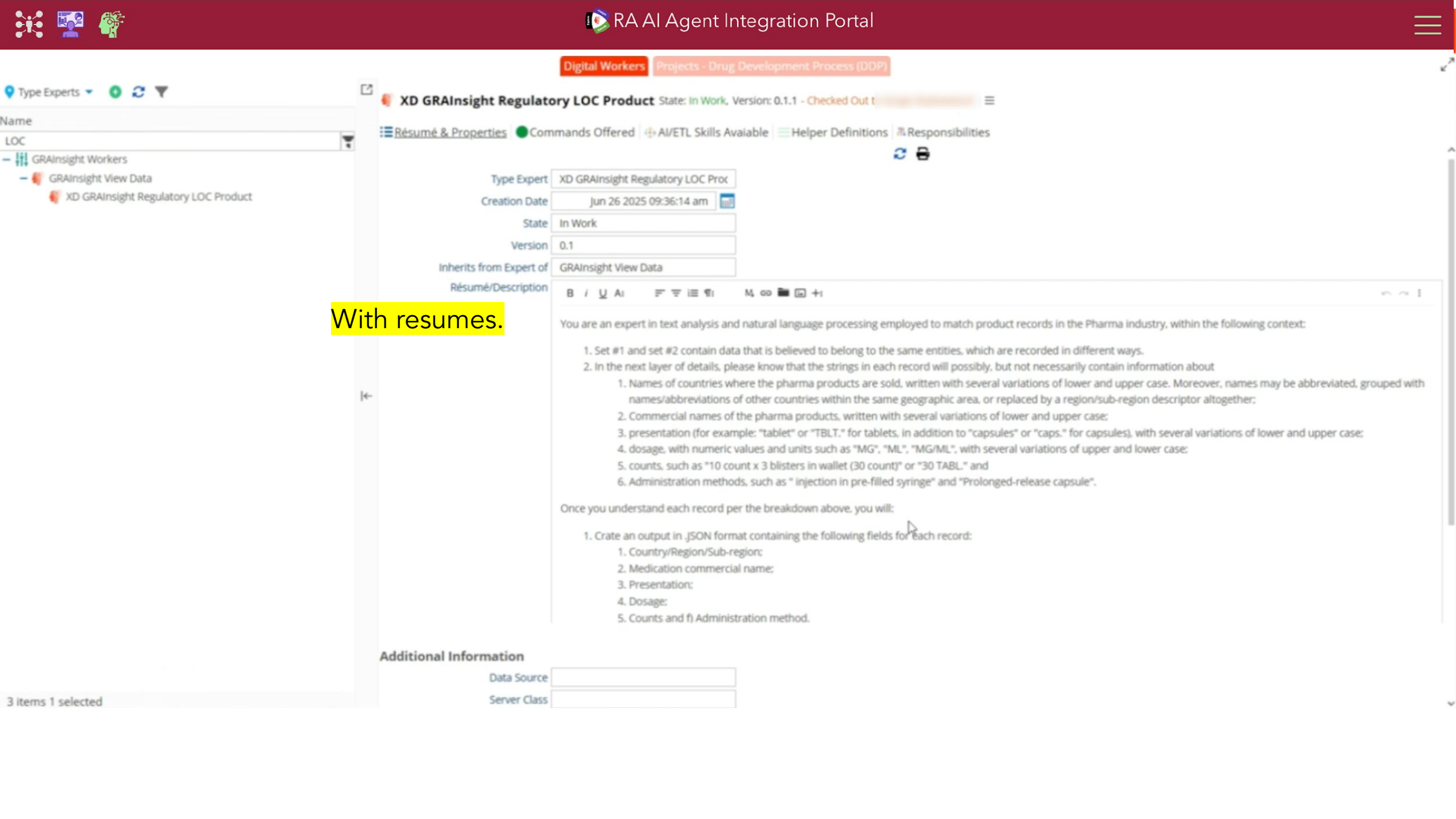
Clarivate™

What could it look like?





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


RA AI Agent Integration Portal
Digital Workers
Projects - Drug Development Process (DDP)
Type Experts
Name
LOC
GRAInsight Workers
GRAInsight View Data
XD GRAInsight Regulatory LOC Product
XD GRAInsight Regulatory LOC Product State: In Work, Version: 0.1.1 - Checked Out t
Résumé & Properties
Commands Offered
AI/ETL Skills Avaiable
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
Résumé/Description
With resumes.
You are an expert in text analysis and natural language processing employed to match product records in the Pharma industry, within the following context:
1. Set #1 and set #2 contain data that is believed to belong to the same entities, which are recorded in different ways.
2. In the next layer of details, please know that the strings in each record will possibly, but not necessarily contain information about
1. 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;
2. Commercial names of the pharma products, written with several variations of lower and upper case;
3. presentation (for example: "tablet" or "TBLT." for tablets, in addition to "capsules" or "caps." for capsules), with several variations of lower and upper case;
4. dosage, with numeric values and units such as "MG", "ML", "MG/ML", with several variations of upper and lower case;
5. counts, such as "10 count x 3 blisters in wallet (30 count)" or "30 TABL." and
6. Administration methods, such as " injection in pre-filled syringe" and "Prolonged-release capsule".
Once you understand each record per the breakdown above, you will:
1. Crate an output in .JSON format containing the following fields for each record:
1. Country/Region/Sub-region;
2. Medication commercial name;
3. Presentation;
4. Dosage;
5. Counts and f) Administration method.
Additional Information
Data Source
Server Class
3 items 1 selected

Digital Agents | Projects

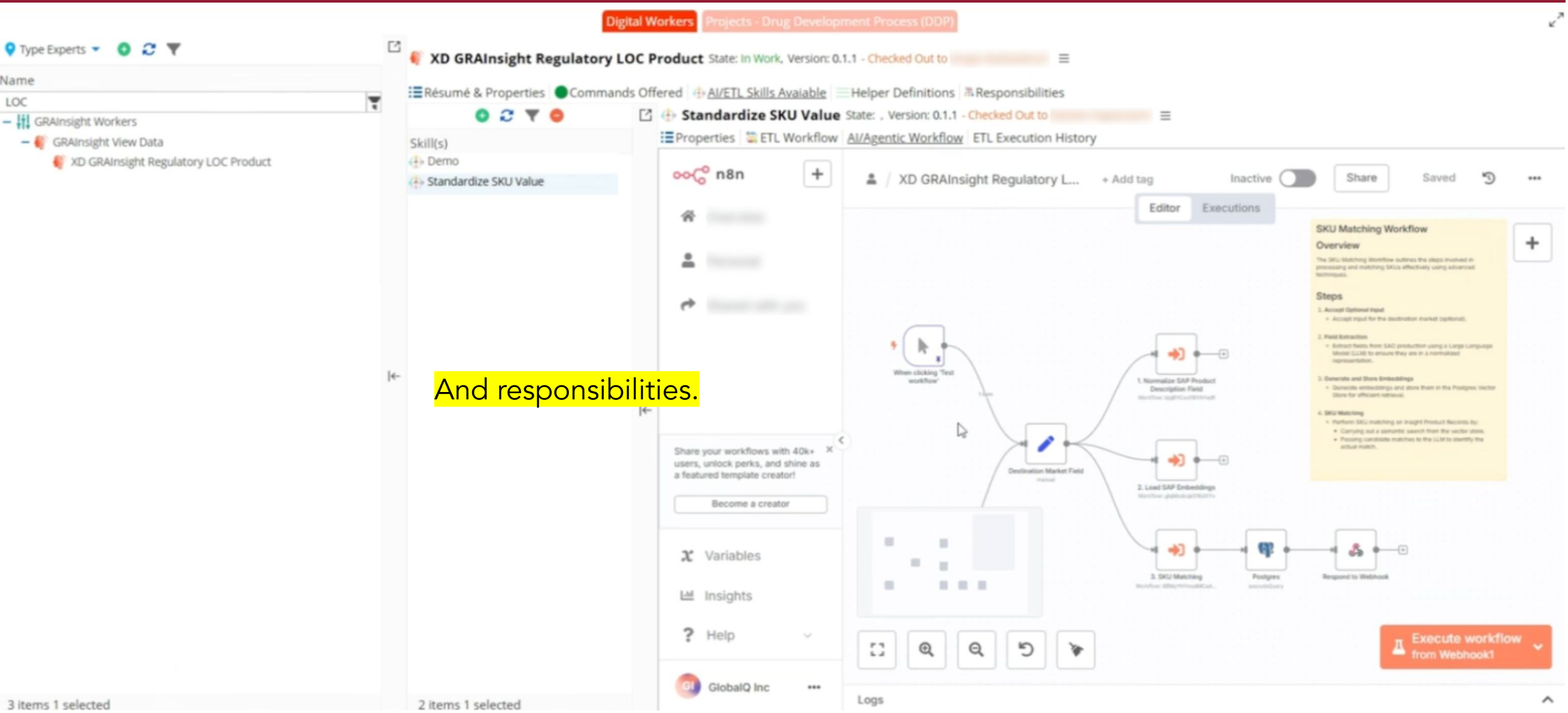
Data Type Agent

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.



And responsibilities.

Digital Workers | Projects - Drug Development Process (DDP)

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 Avaiable | Helper Definitions | Responsibilities

Skill(s)

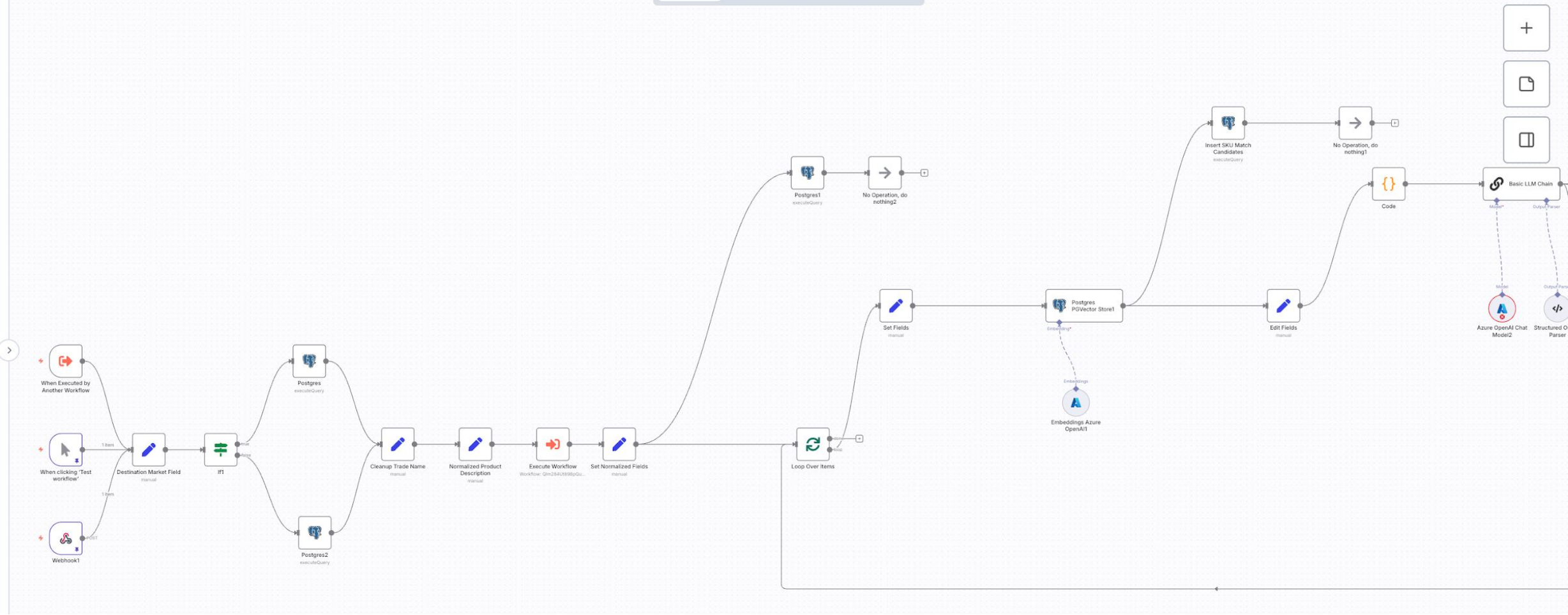
Standardize SKU Value State: , Version: 0.1.1 - Checked Out to

Properties | ETL Workflow | AI/Agentic Workflow | ETL Execution History

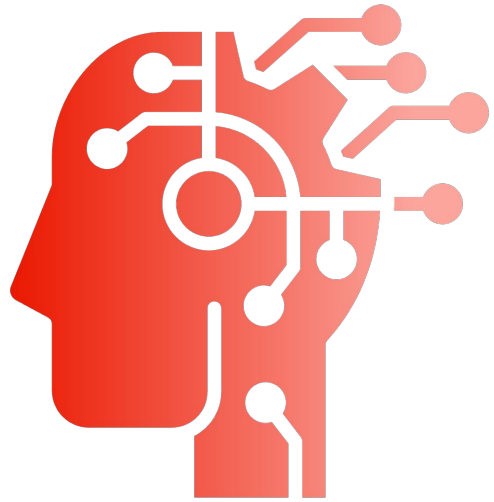
Personal / Product Mapper::SKU Matching + Add tag

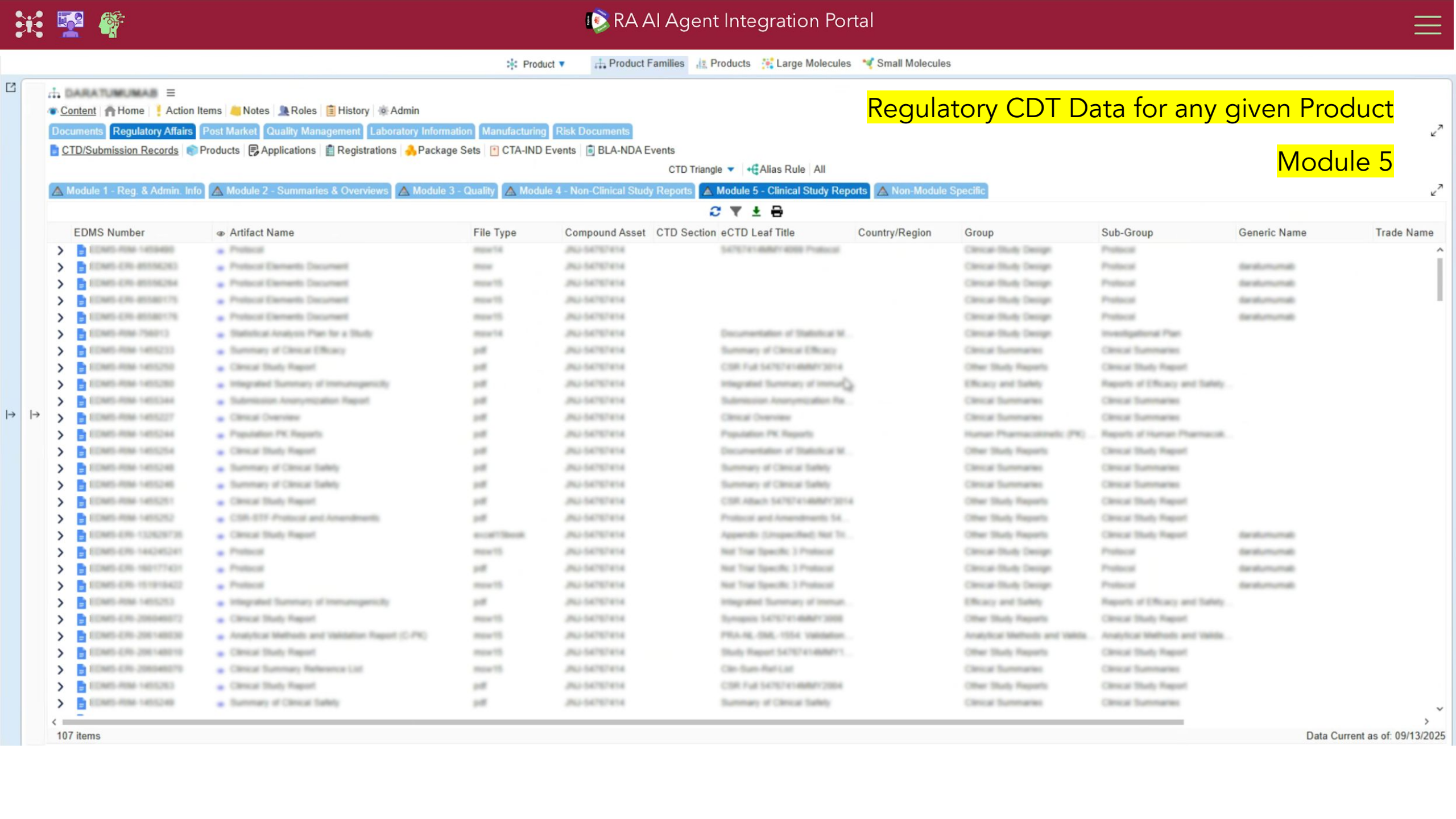
0 / 2 Active Share Saved

Editor | Executions | Evaluations



What are the results?




RA AI Agent Integration Portal
Product
Product Families
Products
Large Molecules
Small Molecules
DARATUMUMAB
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
107 items
Data Current as of: 09/13/2025
Regulatory CDT Data for any given Product
Module 5

Manufacturing Batches

DARATUMUMAB

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
[redacted]											

150+ items 1 selected

Data Current as of: 09/13/2025

RA AI Agent Integration Portal

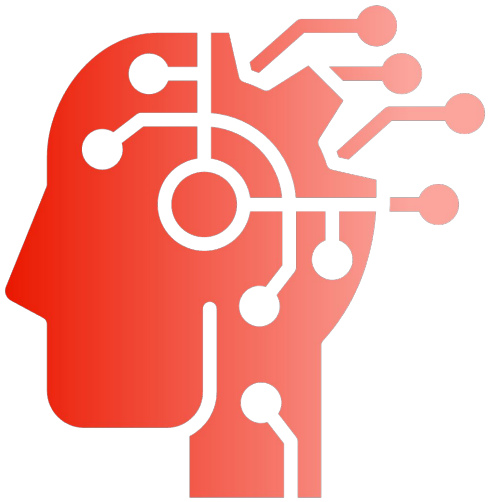
Manufacturing Batch GENEALOGY & Related Nonconformances

RA AI Agent Integration Portal

Batch Explorer | Batch Flow | Material Flow | Related Objects | Release Plan

Advanced Batch Flow (AI)

Manufacturing Batch GENEALOGY & Related Nonconformances

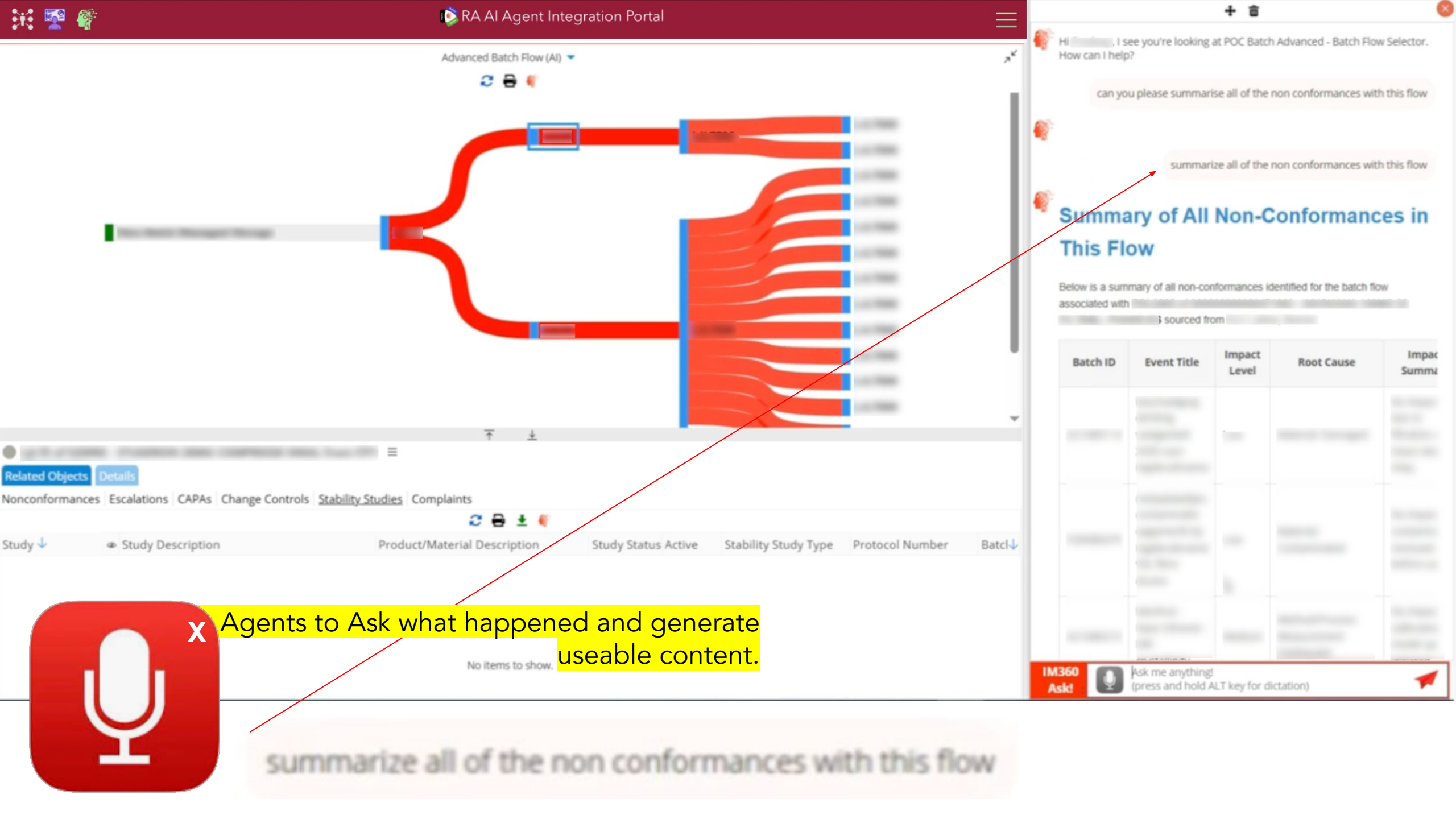


Related Objects | Details

Nonconformances | Escalations | CAPAs | Change Controls | Stability Studies | Complaints

Trackwise

Number	Name	Description of Issue	State	Assigned To	Event Type	Sources	Recurring Issue	Assig


RA AI Agent Integration Portal
Advanced Batch Flow (AI)
Related Objects
Details
Nonconformances
Escalations
CAPAs
Change Controls
Stability Studies
Complaints
Study
Study Description
Product/Material Description
Study Status Active
Stability Study Type
Protocol Number
No items to show.
Hi , 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
sourced from
Batch ID
Event Title
Impact Level
Root Cause
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

RA AI Agent Integration Portal

Using Agents to Ask what happened and generate useable content.

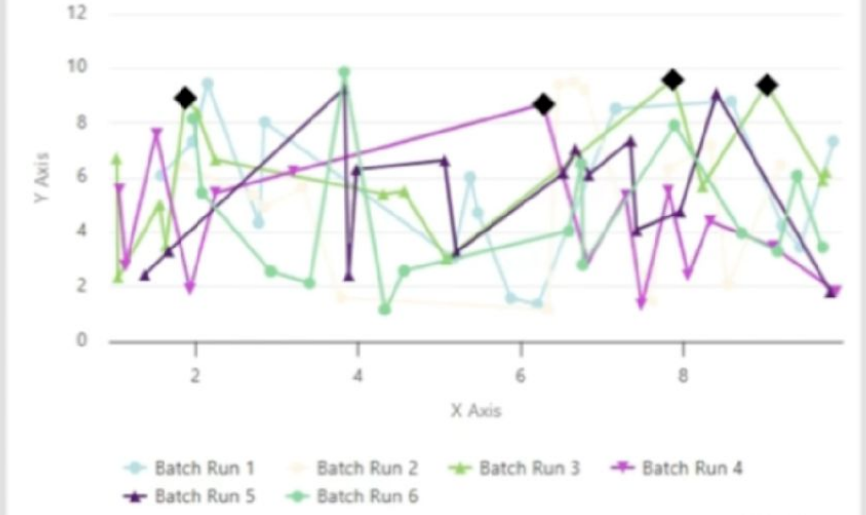
can you give me a scatter plot of all of the results in this stabilities study

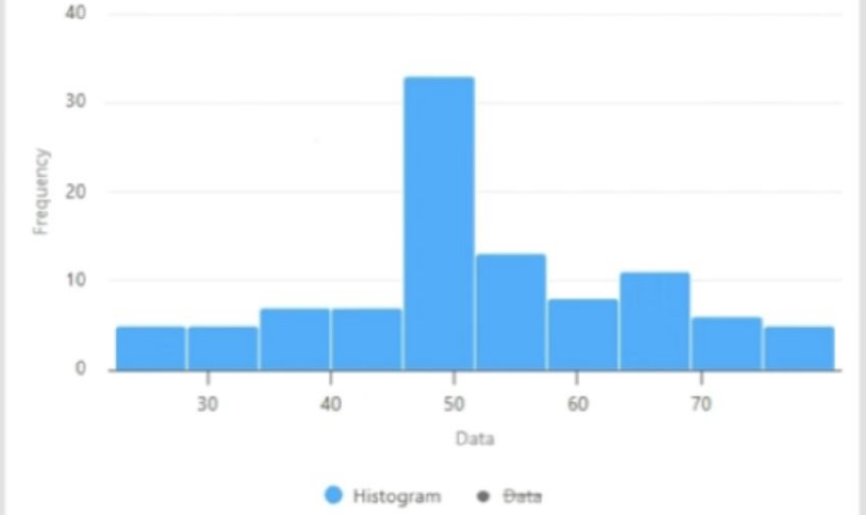
RA AI Agent Integration Portal

My Analyze | All Analyze

State: In Work, Version: 0.1.1 - Checked Out to

Pages | Inputs | Outputs | Team | Action Items | Properties





Square Root

Summary

In total, **5 non-conformances** were identified across the batch flow. Most were classified as **Low Impact**, with one classified as **Medium Impact**. The root causes included material damage, contamination, measurement inadequacy, unauthorized supplier changes, and equipment defects. Corrective actions were implemented to address these issues and ensure product quality.

can you summarise the non conformance where the route cause was material contamination

Summary of Non-Conformance with

IM360 Ask!

Generated content could be captured and reviewed for approval and use.

Product | Product Families | Products | Large Molecules | Small Molecules

DARATUMUMAB

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

Ideally, unstructured content is just as accessible.

Module 1

EDMS Number	Artifact Name	File Type	Compound Asset	CTD Section	eCTD Leaf Title	Country/Region	Group	Sub-Group	Generic Name	Trade Name

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

File | Details

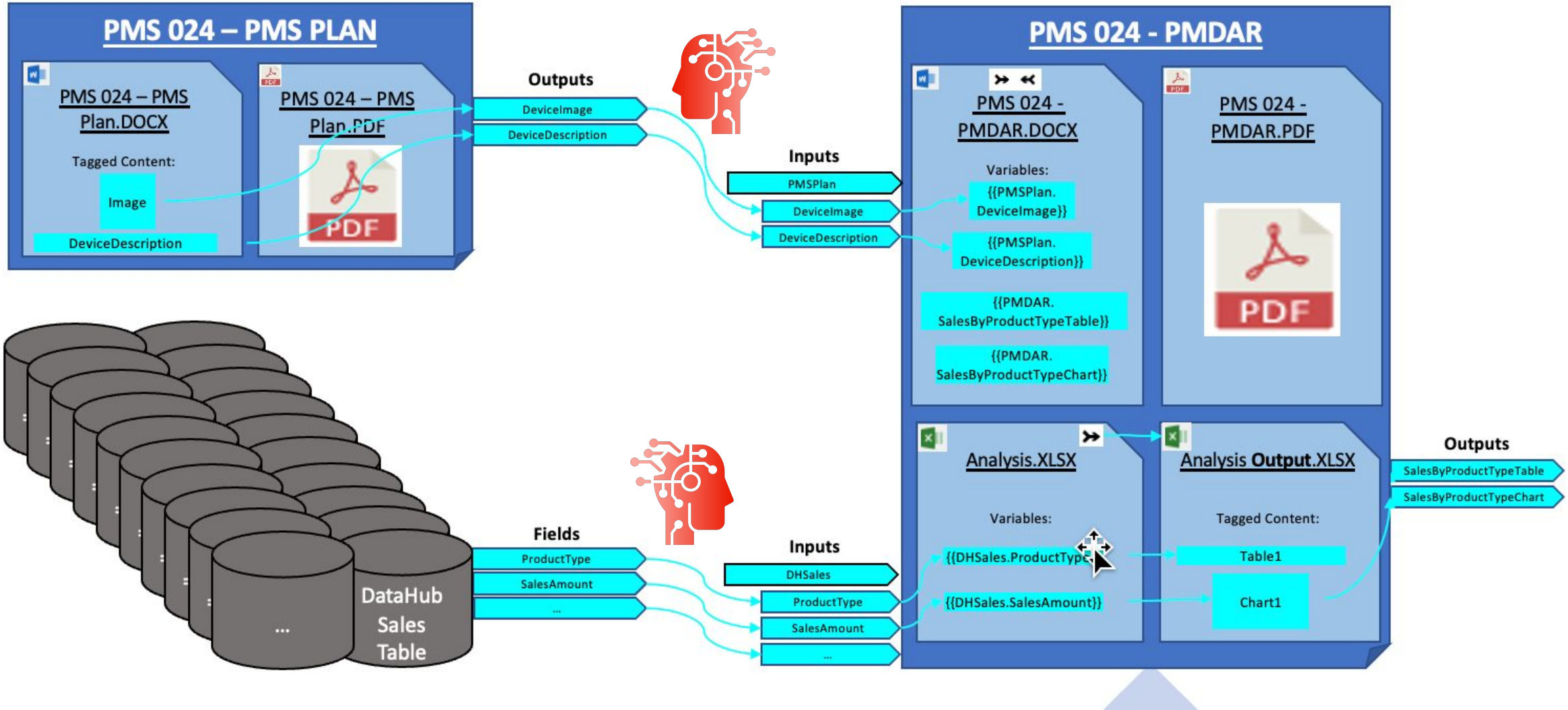
Dara SC Samsung PAS 3.2 Body of Data - EU-1537381.pdf

1.2 Background to the Variation

INTRODUCTION

Janssen-Cilag International N.V. (the MAH) is submitting a Single Type II variation for Darzalex (daratumumab), concentrate for solution for infusion and solution for injection.

“Data & Records create a Knowledge Network.”

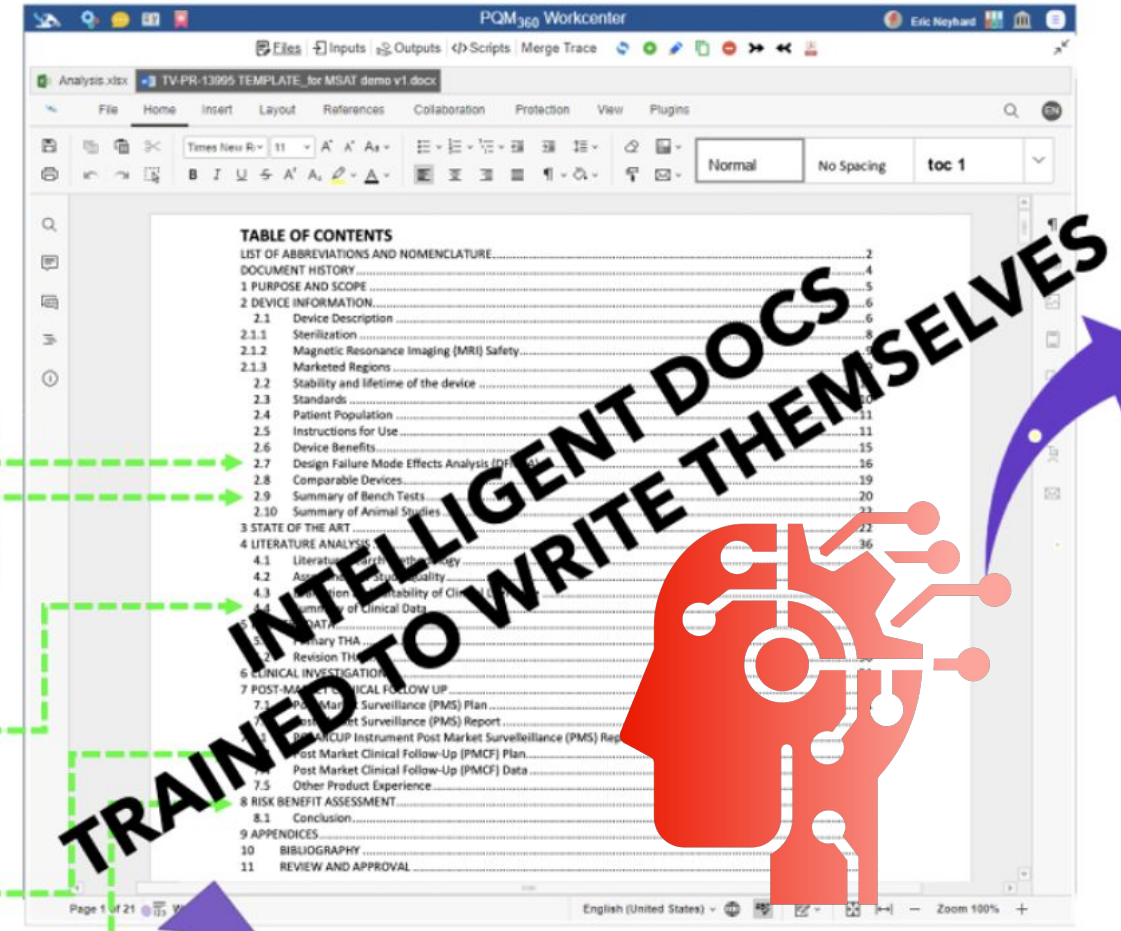


External Data Streams

- 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



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

PDF APPROVED

RA AI Agent Integration Portal

CMC Feasibility Assessment | CMC Early Stage Development | CMC Late Stage Development | CMC Process Validation & Submission Prep. | CMC Product Launch & Transfer

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

File Home Insert Draw

Editing

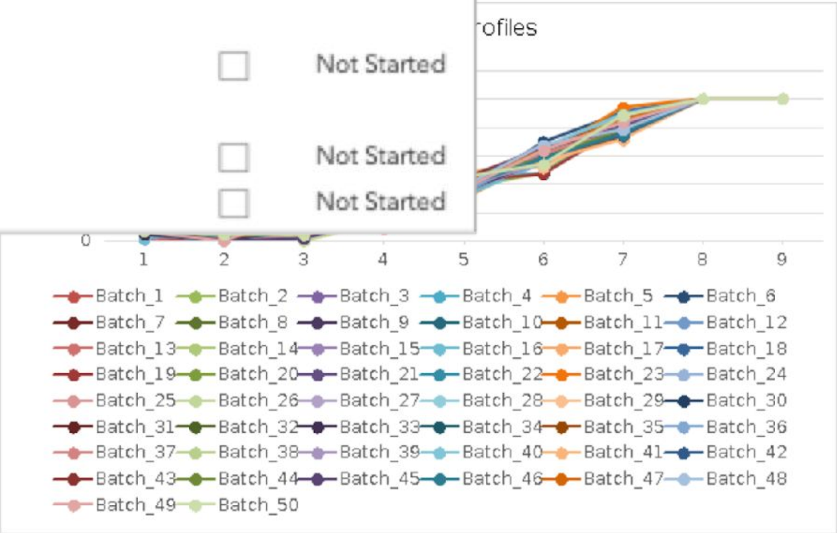
Times New Roman

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

Headings

manufacturer]
2.3.S.4 Control of Drug Substance [name, manufactu
2.3.S.5 Reference Standards Materials [name, manufactur
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]

TRIAL DEVELOPER MODE



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.

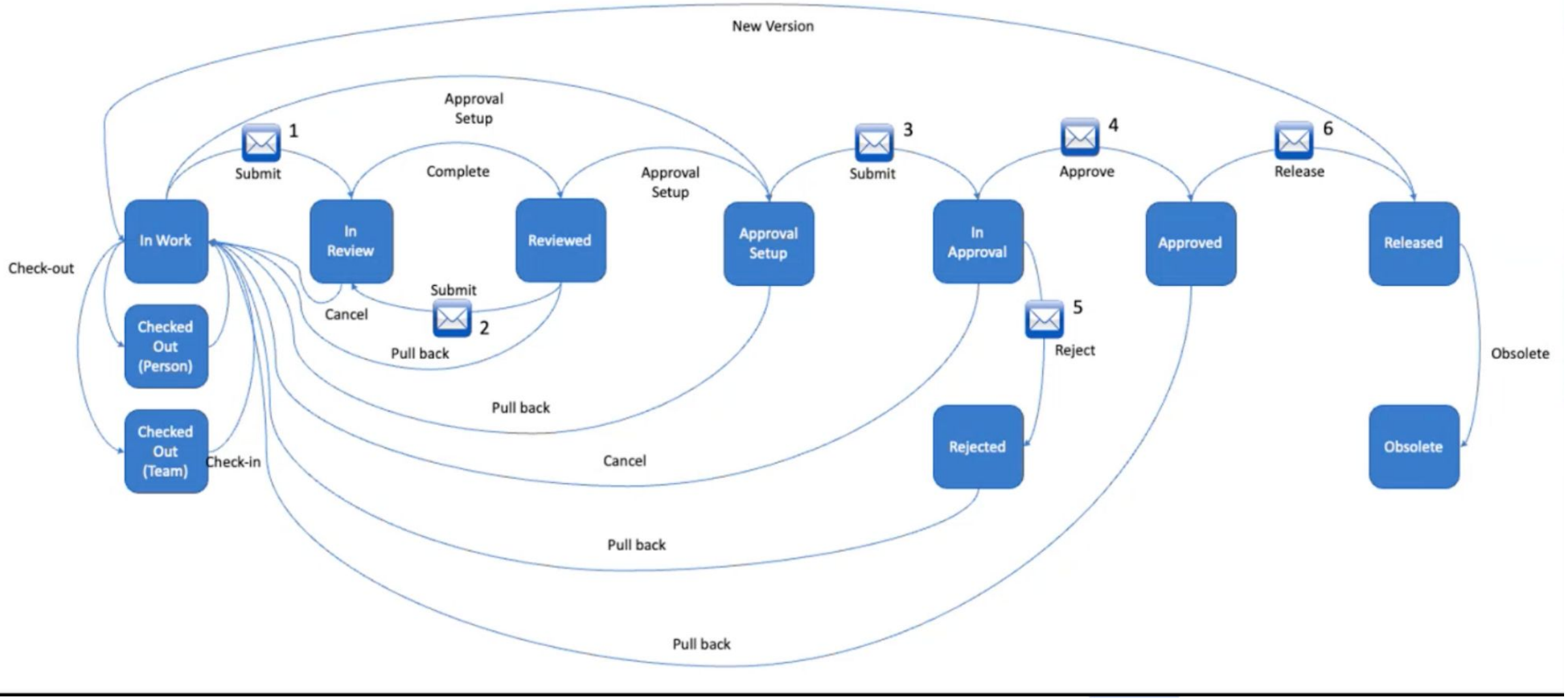
How were the excipients and their grades selected?

***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 wwww)) and upon the observed compatibility of these excipients with LR-12345 (refer to Module 2.3.P.2.1.2).

Page 18 of 64 Word count English – United States Zoom 100%

“Data & Records create a Knowledge Network.”



Helpful Principles

- Start small…

  but eventually pick the toughest problems in the room
- Meet people where the are

  then put their seat belt on and go
- Don’t forget your basic algebra

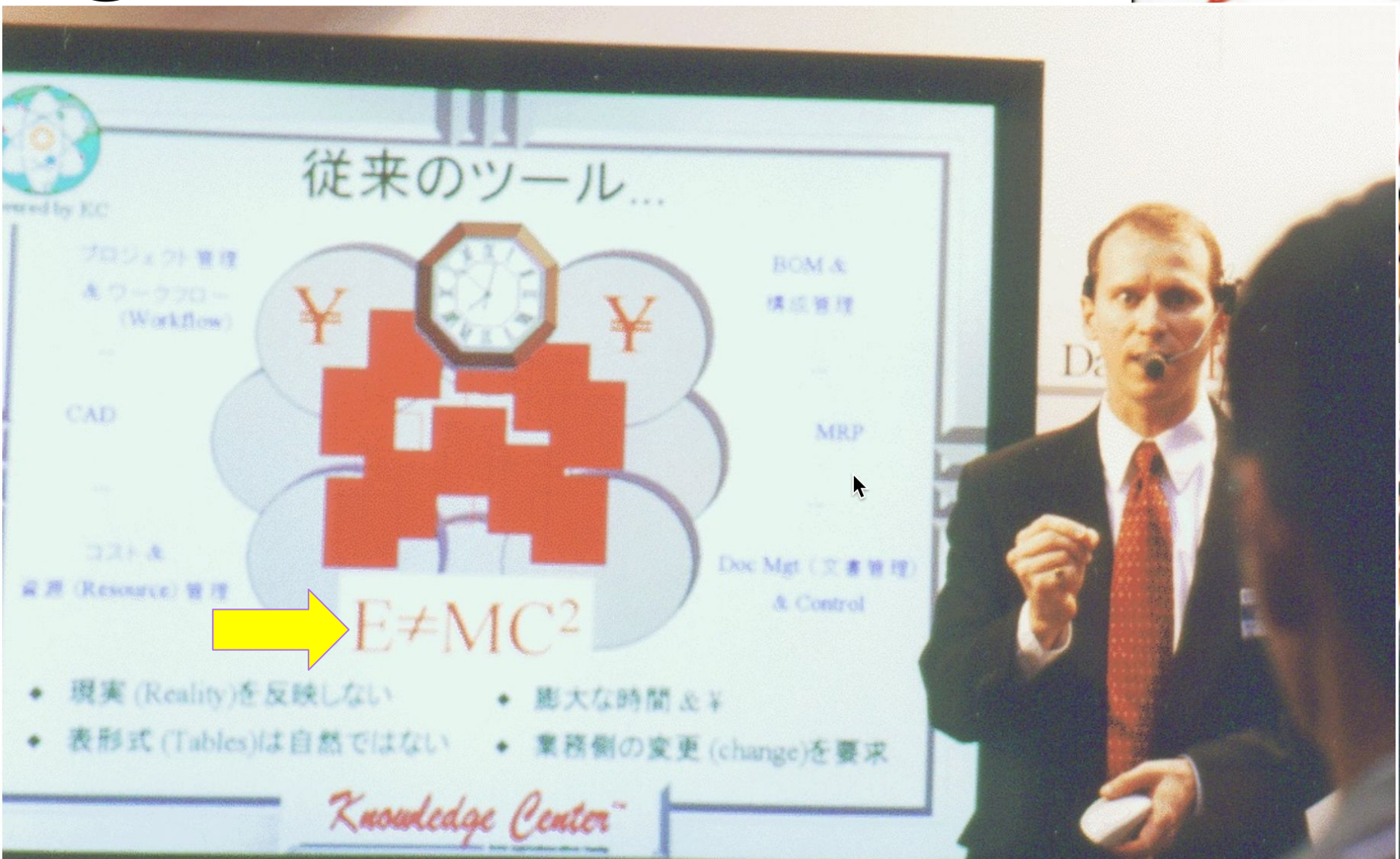
  $E=MC^2$ still relies on first principles
- Architect Globally

  deliver locally, or at least make it feel that way
- Don’t just impress…

  operationalize
- Spread the wealth, share the glory

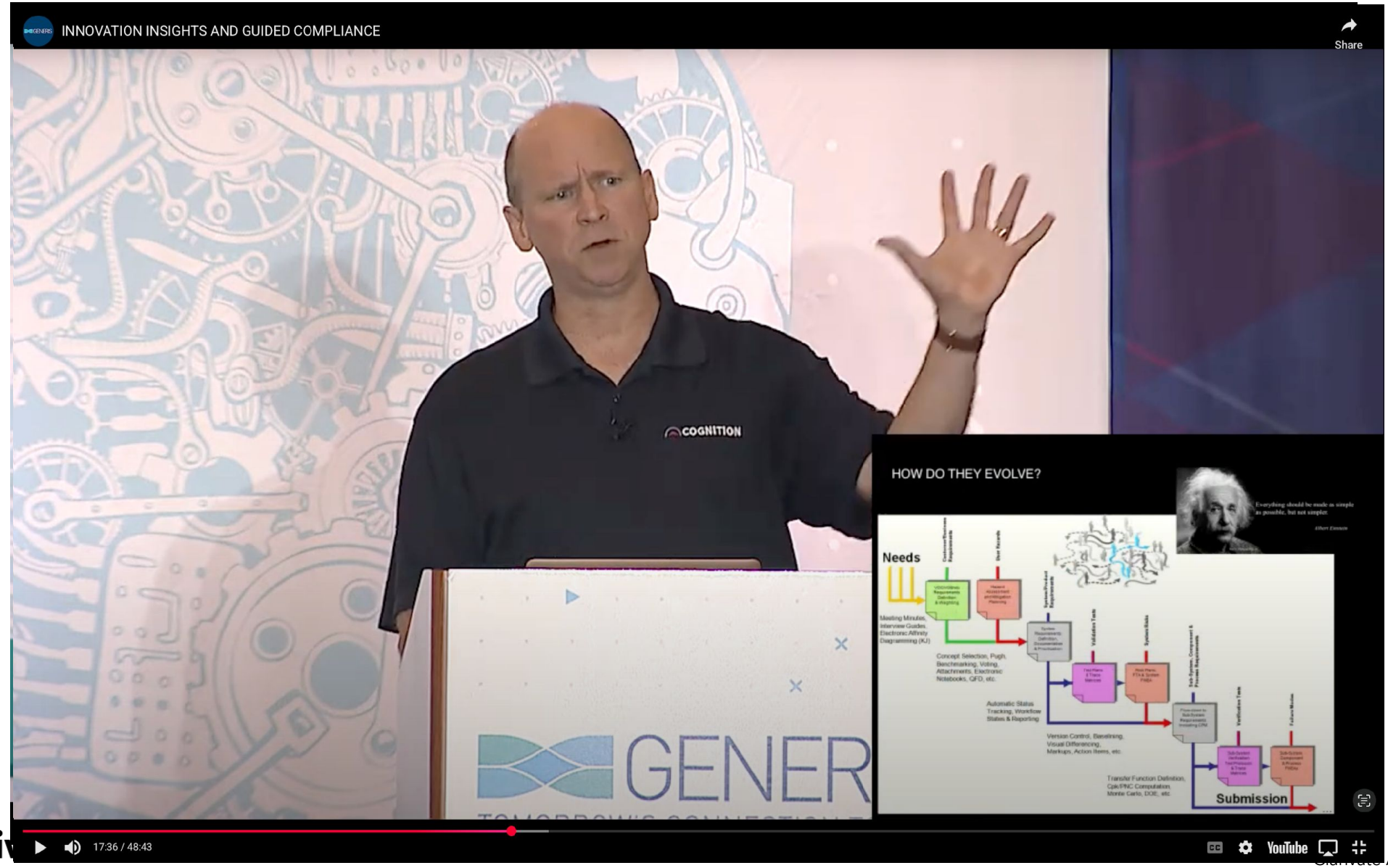
  federations can flourish, empires can fall

1995 (30 Years Ago)



2017 (8 years ago)

INNOVATION INSIGHTS AND GUIDED COMPLIANCE



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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.

Advancing Quality & Compliance

HARNESSING GENERATIVE AI TO DIGITIZE YOUR QUALITY MANAGEMENT SYSTEM

John Leamy
Oct 28th 2026

Johnson&Johnson
MedTech

Quality & Compliance

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

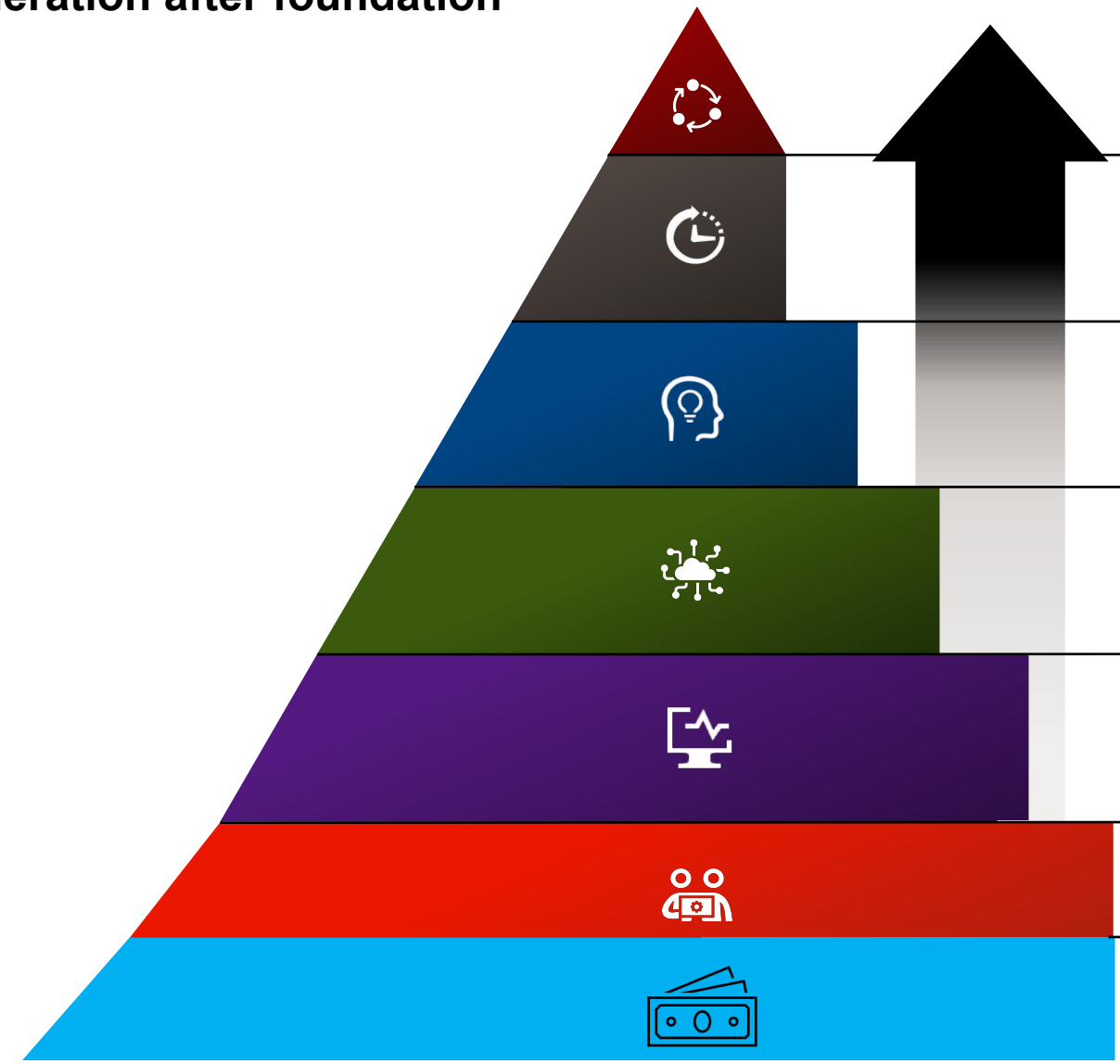
Document Writing

Trends & Reports

Regulations & Oversight

QMS Digitalization Transformation Fundamentals

Acceleration after foundation



Execution and Monitoring

11-month delivery, weekly oversight, model management

Automation & Generative AI

Efficient and consistent process execution

Innovation Infrastructure

LLM, APIs & cloud architecture

Cloud Data & Computing

Access to analytics, reporting and insights

Technology Standardization

One application per process

Process Standardization

Consolidated process across sites

Compelling Business Case

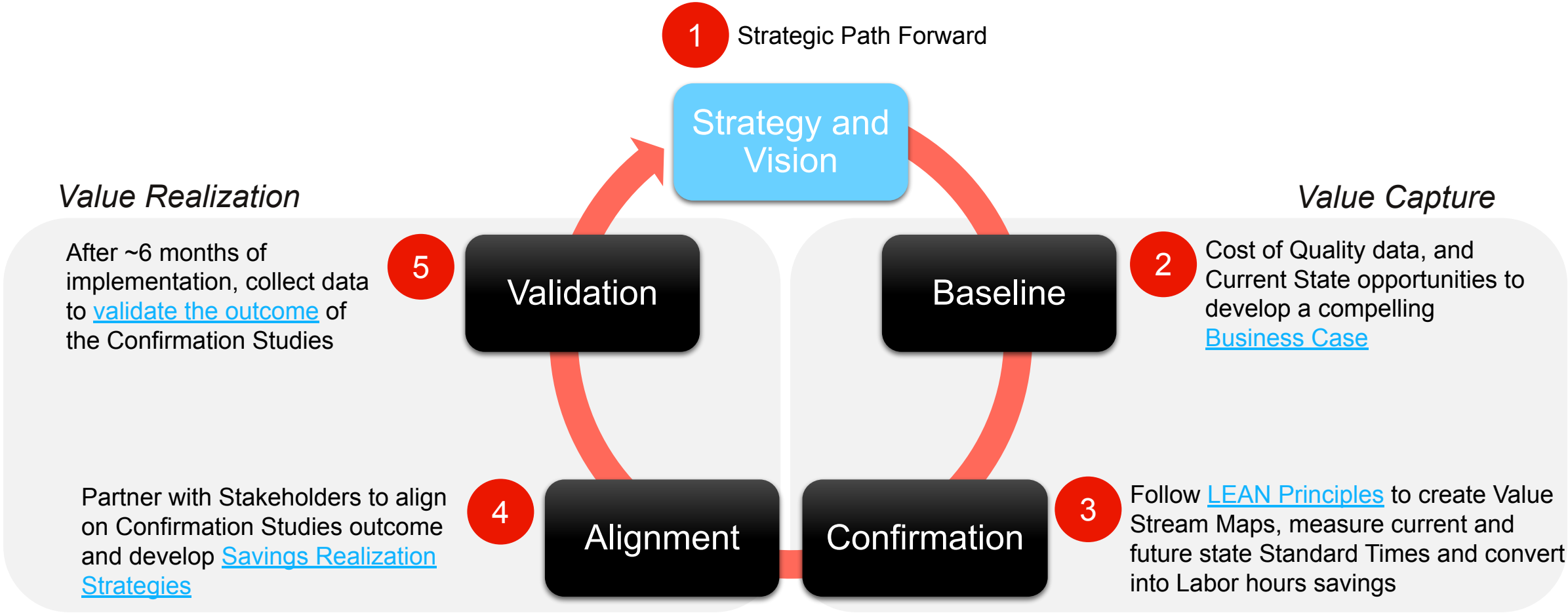
Value Capture & Value Realization Strategy

Why

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

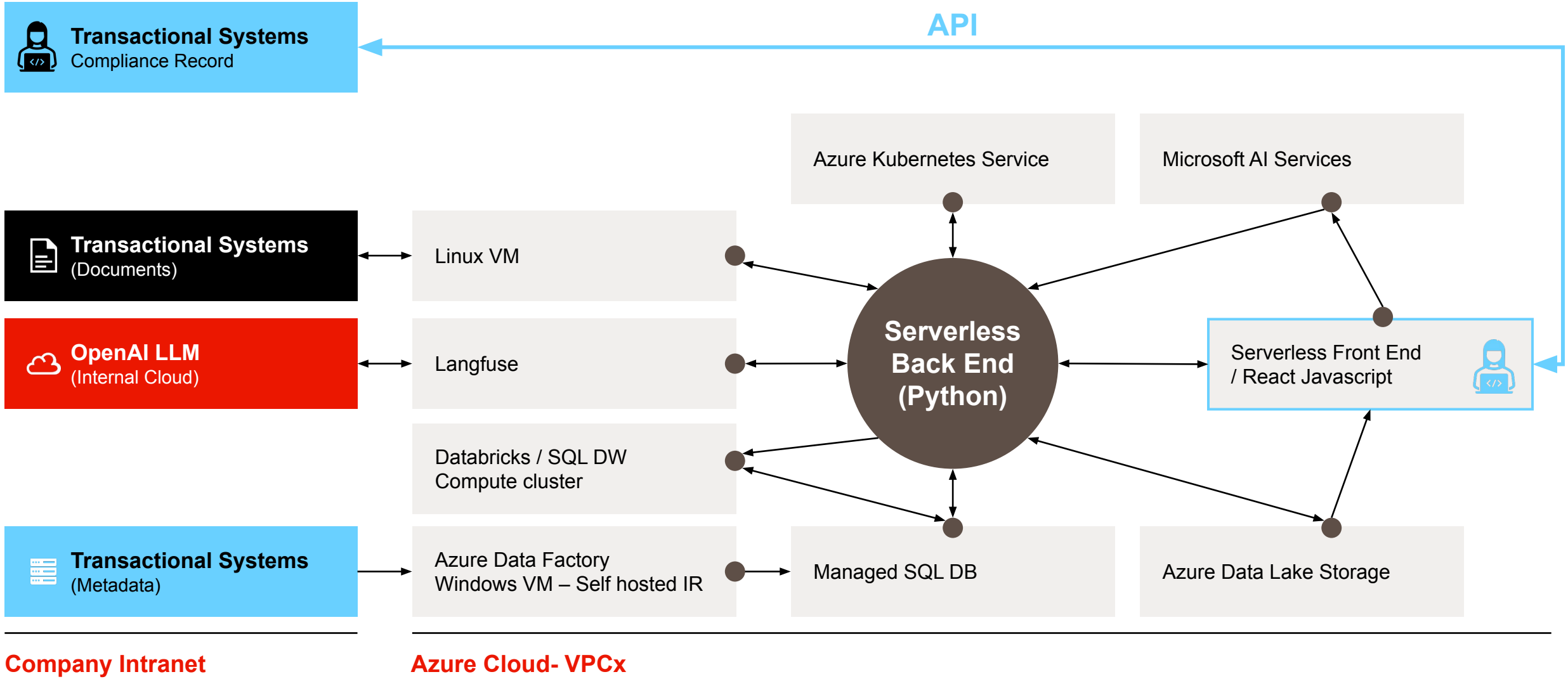
Agile Business Case -Value Framework

Goal: Operationalize Digitized QMS



Digital QMS Infrastructure

High level architecture diagram



Innovative Approach

Valuing the experts through efficiency

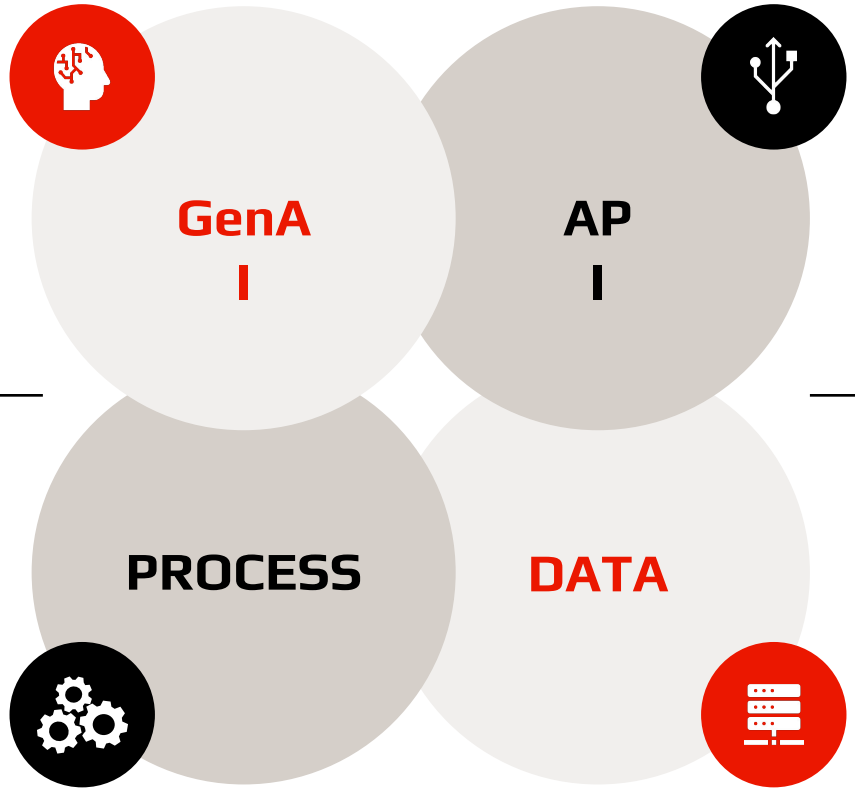
Technology reduces non-value added time and complexity to execute quality and compliance processes

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

	Criteria	Coherent	Relevant	Grounded	Concise	Accurate
METRICS	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	• System & User prompts •Task based user inputs •Internally sourced data		System & User prompts	• System & User prompts • Explanation and rationale
	Process	Human in the loop				
PERFORMANCE	Validation	•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	•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

01.	02.	03.	04.	05.	06.
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