AI Beyond the Lab

Processes to Drive Enterprise Adoption

Agenda

- Introduction and Background
- Formulation of AI Use Cases
- AI Governance and AI Scorecard
- Validation and Quality Assurance
- Recommendations and Best Practices for AI at Scale
- Top Organon Use Cases for AI with Ennov Demo
- Q&A

Organon’s AI Journey - Introduction

- **Challenge:** Enterprise-level AI required governance, validation, and scalability while delivering value quickly.
- **Solution:** Developed and iterated an AI scorecard to evaluate, prioritize, and govern AI initiatives.
- **Lessons Learned:**
  - Embed governance early
  - Use pragmatic, risk-based validation approaches
  - Partner with mature vendors who combine tech + compliance expertise
- **Top Use Cases:**
  - Response to Health Authority Inquiry
  - Regulatory Intelligence via Chatbot
  - Dossier / Content Creation
- **Impact:** Early wins can demonstrate measurable value today while building a foundation for AI at scale.

Definitions

- AI: "AI can generally be described as a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions, and making predictions.”*
- ML: “Considered a subset of AI that allows ML models to be developed by ML training algorithms through analysis of data, without models being explicitly programmed. Additionally, there are a variety of ML methods and different types of algorithms that may be utilized in a given context.“*
- GenAI: “Generative artificial intelligence (GenAI) systems create new content – including text, image, audio, and video – based on their training data and in response to prompts.“**

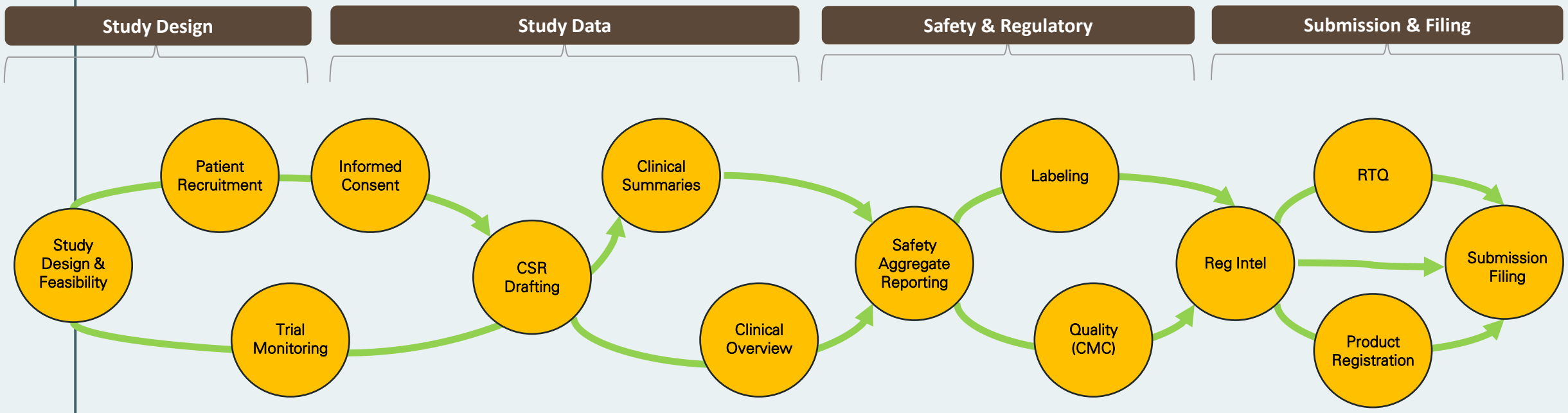
*FDA Discussion Paper, Using Artificial Intelligence in the Development of Drug and Biological products, 2023, lines 26-31
** OECD 2023 AI Policy Paper

Evolution of AI

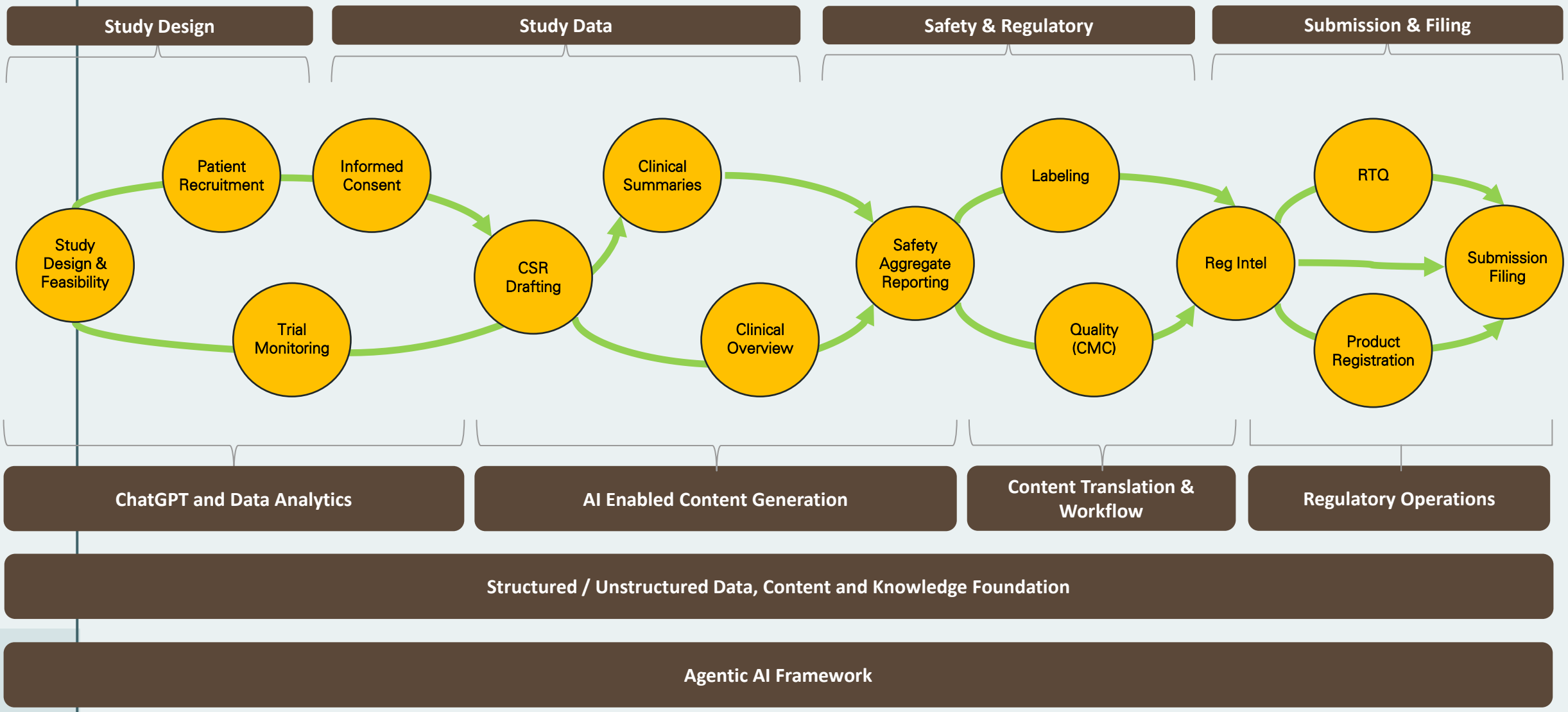
- Explosion of Digital Data
- Specialized processing (GPUs)
- Algorithm Advancement

Formulation of R&D AI Use Cases

AI Use Case Analysis Across R&D (The Ask)



AI Use Case Analysis Across R&D (The Breakdown)



Other Ways AI Can Help!

Audit Trail Analysis

Unauthorized access, suspicious modifications

SDLC Content Creation

Such as Requirements Specifications, Test Cases

Automated System Validation

AI-driven testing

Electronic Signatures

Ensure no attempts to tamper or reuse signatures

Data Quality and Integrity

Flag potential errors/inconsistencies

Training and System Provision

Track training vs access to systems

Data Retention and Archiving

Manage retention schedules and automate process accordingly

System Change Controls

Automate impact analysis, testing, validation

AI Use Case Analysis Across R&D (Reality)

- Everyone is asking for AI
- Leadership wants AI to bring operational efficiency
- Unrealistic Expectation (ChatGPT can do everything)
- Internal Tools and Resources
- Understanding Vendor Roadmap and Priority
- Computing Power is not Free (tokens)
- Investment vs Return
- Application Footprint – Single end to end platform or best of breed applications?
- Garbage-In and Garbage-Out (Hallucination)
- Validation and Quality Assurance (Prompt Management)

Enterprise IT institute AI Council and Factory to evaluate and manage demands

AI Governance and Scorecard

Governing AI is essential to guarantee that its evolution and application are handled responsibly, allow for innovation while emphasizing our company's ethical principles.

AI Council Check List:

- AI council use case (standard template)
- AI Prioritization Rubric (if investment is required)
- Vendor solution architecture, including LLM details
- Vendor agreement with our companies standard AI language included

What do we consider Internal?

An AI use case developed, deployed, or managed either directly by our company or by third party under our supervision and control.

Examples:

- Our own version of ChatGPT
- Social media AE monitoring

What do we consider External?

An AI use case utilized by third party service providers as part of their service offering to our company, where we have no direct supervision or control over their development, deployment or management.

Examples:

- Ennov RTQ
- AI offering from Service Now to manage support tickets

AI Factory Life Cycle

Education sessions focusing on illustrating the art of possible with AI

Demonstrate practical examples of how AI can be applied to specific business needs (prompting)

Identify pain points and uncover opportunity in AI

Host targeted deep dive with functional teams

Assess rough order of magnitude value of the solution

State the business issue and quantifying value, efforts, and alignment to strategic goals

Evaluate using AI council rubric for prioritization

Present the business and rubric to AI council

Gather feedback

Confirm solution prioritization and next steps

Prioritize key features and develop wireframes to visualize future experience

Design and validate the technical architecture to support final solution

Test, validate and deploy AI solution

Conduct training

Plan for SOPs

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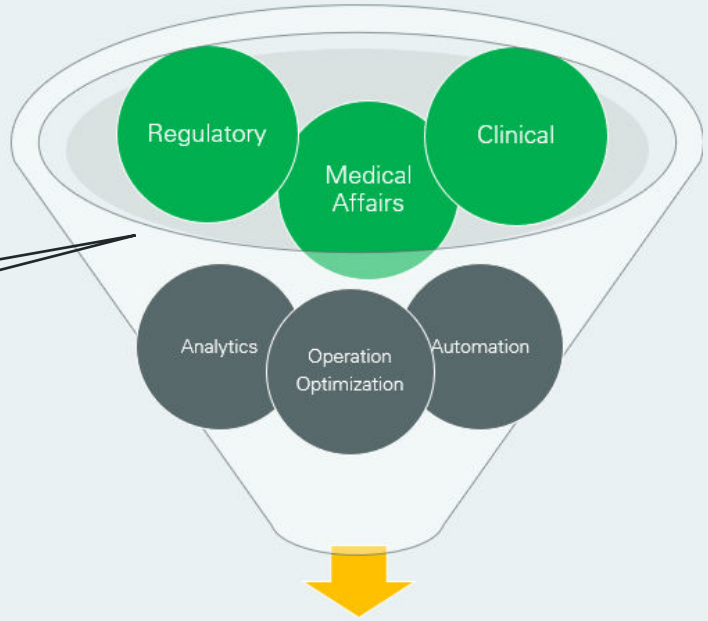
AI Factory Life Cycle

0. AI Education → 1. Discovery → 2. Business Case → 3. Prioritization → 4. Functional Design → 5. Technical Design → 6. Delivery

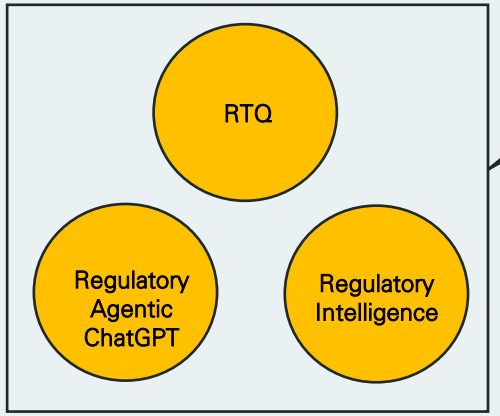
Stage Gate

Business Case



Prioritization

Pass Stage Gate



Delivery

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Example: AI Business Case Rubric (Score Card)

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Investment Estimation	10	7	5	3	1
	Low	Minor	Medium	Material	High
Development Cost – Build vs Buy (SDLC, Testing and GxP Controls)	<$250k	$250k – $500k	$500k – $750k	$750k – $1.5M	>$1.5M
Run Cost – Annual MS&O (Compute & License Cost)	<$50k	$50k – $100k	$100k – $200k	$200k – $300k	>$300k
Value Estimation (Yearly)	10	7	5	3	1
	High	Material	Medium	Minor	Low
❑ Revenue Driver ❑ Customer Engagement ❑ Transformation ❑ Cost Efficiency ❑ Competitive Advantage	> $2M	$1M – $2M	$500k – $1M	$250k – $500k	<$250k
Time to Value (month)	< 3	3-6	6-9	9-12	>12
Reuse Potential	High	Medium	Partially	Limited	One-off
AI Readiness	10		5		0
Compliance – Alignment to risk level as defined by company policy	Low Risk Use Case		Regulatory obligations and patient safety		High Risk
Data – Availability, Garbage in/out	Available and clean		Partially available		Issues
Strategy – Approved LLM, agentic framework…	Available in-house		Vendor delivered		Major Gap
Resources – Talent, FTE, FTC	Available		Require hiring		Major Gap

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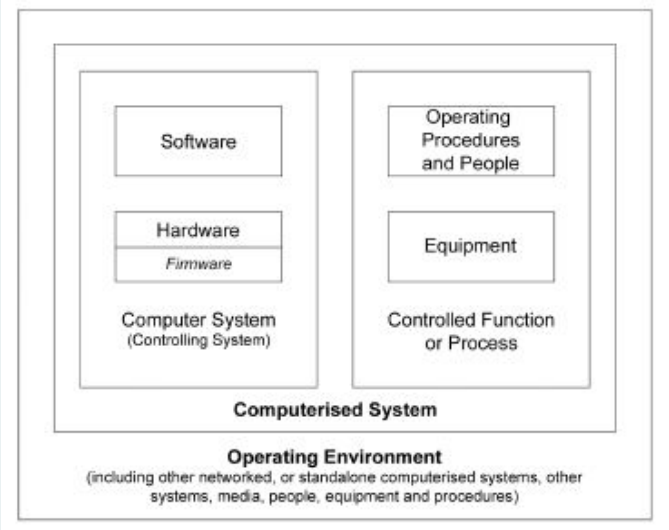
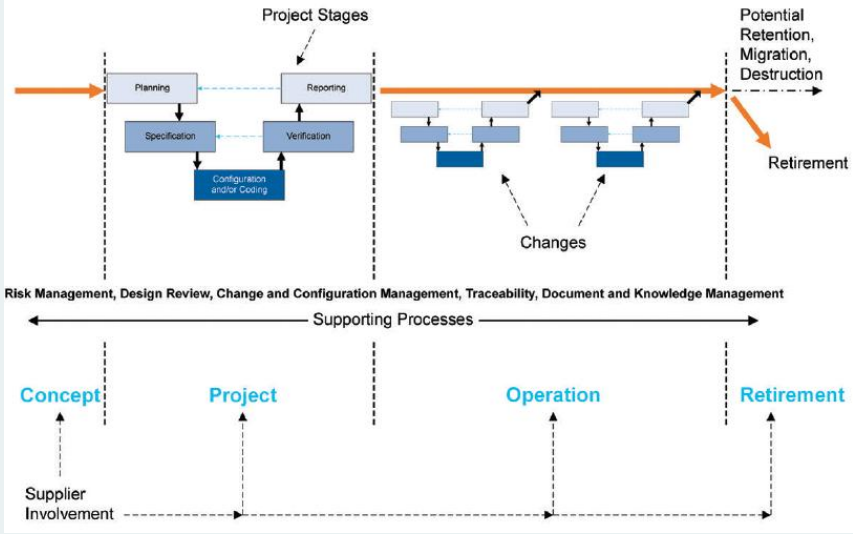
Validation and Quality Assurance

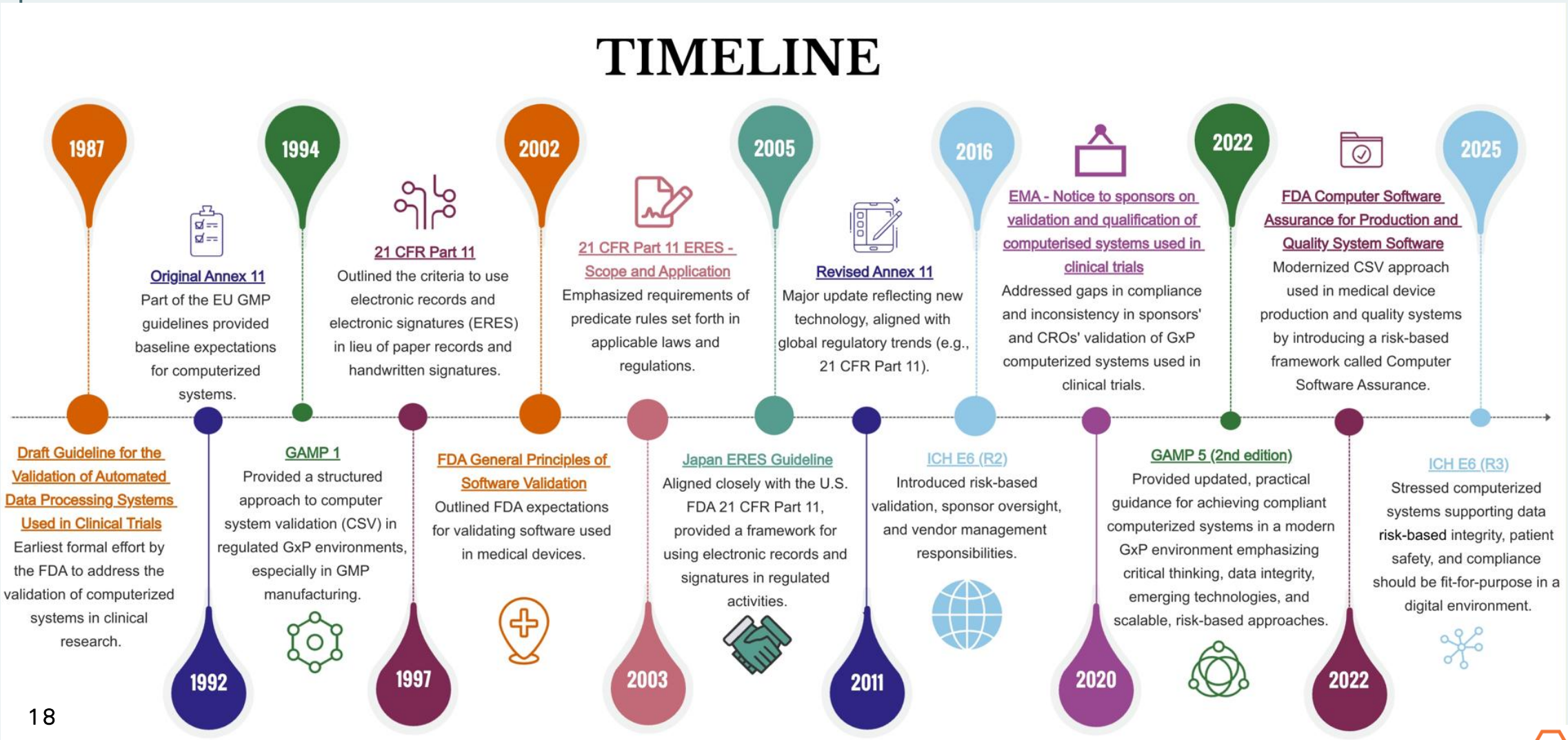
Basics of System Validation

- Computerized System – Includes SOPs
- Fit for Purpose – Intended Use
- “Documented” Evidence – Proving compliance and traceability
- Risk Based Approach – Focus on Product Quality, Patient Safety, Data Integrity
  - Utilize Vendor Documentation
- Lifecycle Perspective – Initial requirements though system retirement





Key Guidelines and Regulations



Typical Validation Deliverables

Validation Deliverable	GAMP Cat 3 (non-configurable)	GAMP Cat 4 (configurable)	GAMP Cat 5 (bespoke)
GXP Assessment	X	X	X
Risk Assessment	X	X	X
Validation Plan	X	X	X
User Requirements (URS)	X	X	X
Functional Requirements (FS)	X - Vendor owned	X - Vendor owned	X, but potentially Vendor owned
System Design Spec (SDS)	X - Vendor owned	X - Vendor owned	X, but potentially Vendor owned
Configuration Spec (CS)		X, but potentially Vendor owned	
IQ Protocol, Test Scripts, Summary	X - Vendor owned for SaaS	X - Vendor owned for SaaS	X, but potentially Vendor owned
OQ Protocol, Test Scripts, Summary	X - Vendor owned	X - Vendor owned for SaaS	X, but potentially Vendor owned
PQ/UAT Protocol, Test Scripts, Summary	X, but potentially vendor owned	X – Includes URS/CS testing	X
Trace Matrix	X – URS to PQ/UAT scripts	X – URS/CS to PQ/UAT scripts	X – Depending
Validation Summary Report	X	X	X
SOPs (Business / IT)	X	X	X
Training Records (User Access)	X	X	X

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Validation Best Practices

- Involve QA early and throughout the process
- Take a risk-based approach to validation
  - With the FDA CSA guidance this might include updating SOPs
- Test GAMP Cat 4 software following the business process
- Rely on vendor documentation
- System Operations – Validation does not end until system is retired, Periodic Reviews
- Business Continuity Plan, RTO/RPO considerations
- SOPs for Incident, Problem and Change Management / User Access

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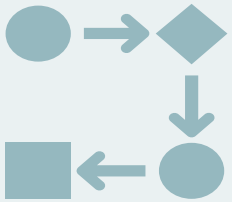
The AI Twist to Validation

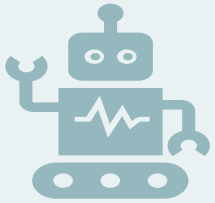
Concept Phase

- Assess the Business Capabilities and Needs
- Understand the intended use, how the model should behave and be applied, and how can the outcome be trusted
- Prototype
- Focus on Data Strategy and Build a Strong Data Governance – Unified platform
- GXP Assessment



Development Phase

- Clear Requirements
- Iterative Development including Model Design/Selection
- Robust Evaluation
- Seamless Integration
- Verification and Release
- Test Data Set for Development, Validation/Training Data set for Testing



Operational Phase

- Continuous Oversight
- Change Management
- Data-Driven Improvements
- Rigorous Re-evaluation and Periodic Reviews
- Performance Monitoring
- Human in the Loop
- Production/Live Data Set

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Recommendations and Best Practices for AI at Scale

Ways to Increase Trust in AI

- Align every AI initiative with business goals
- Start Small and Iterate – Get Quick Wins
- Have a clearly articulated ROI - Establish measurable outcomes
- Understand the Data and AI outcomes - why a model made a given decision
- Ensure Data Governance Mechanisms are in place
- AI Training for Internal Teams – Teams should understand what AI can / cannot do
- Ensure Change Management is in place
- Human in the Loop

AI – Tips and Tricks

Proactive Risk Management

Identify and assess ML-specific risks, including data quality, vendor reliance, model maturity, and system performance. AI decisions must be documented and explainable.

Dynamic vs. Static Systems

Apply traditional change management for static models; implement ongoing monitoring and controls for dynamic, continuously learning systems.

Strong Data Governance

Ensure data quality, relevance, and structure align with project goals and performance metrics from the outset.

Unified platform. Data Bias – cannot use poor quality data sets for training.

Structured Change Management

Integrate clear processes to manage iterative changes, including regulatory deliverables (GXP). AI based systems must be validated and as learning models change – re-validation

Continuous Monitoring

Conduct periodic reviews to detect and correct bias, overfitting, and system degradation over the model's lifecycle.

Top Organon Use Cases for AI with Ennov Demo

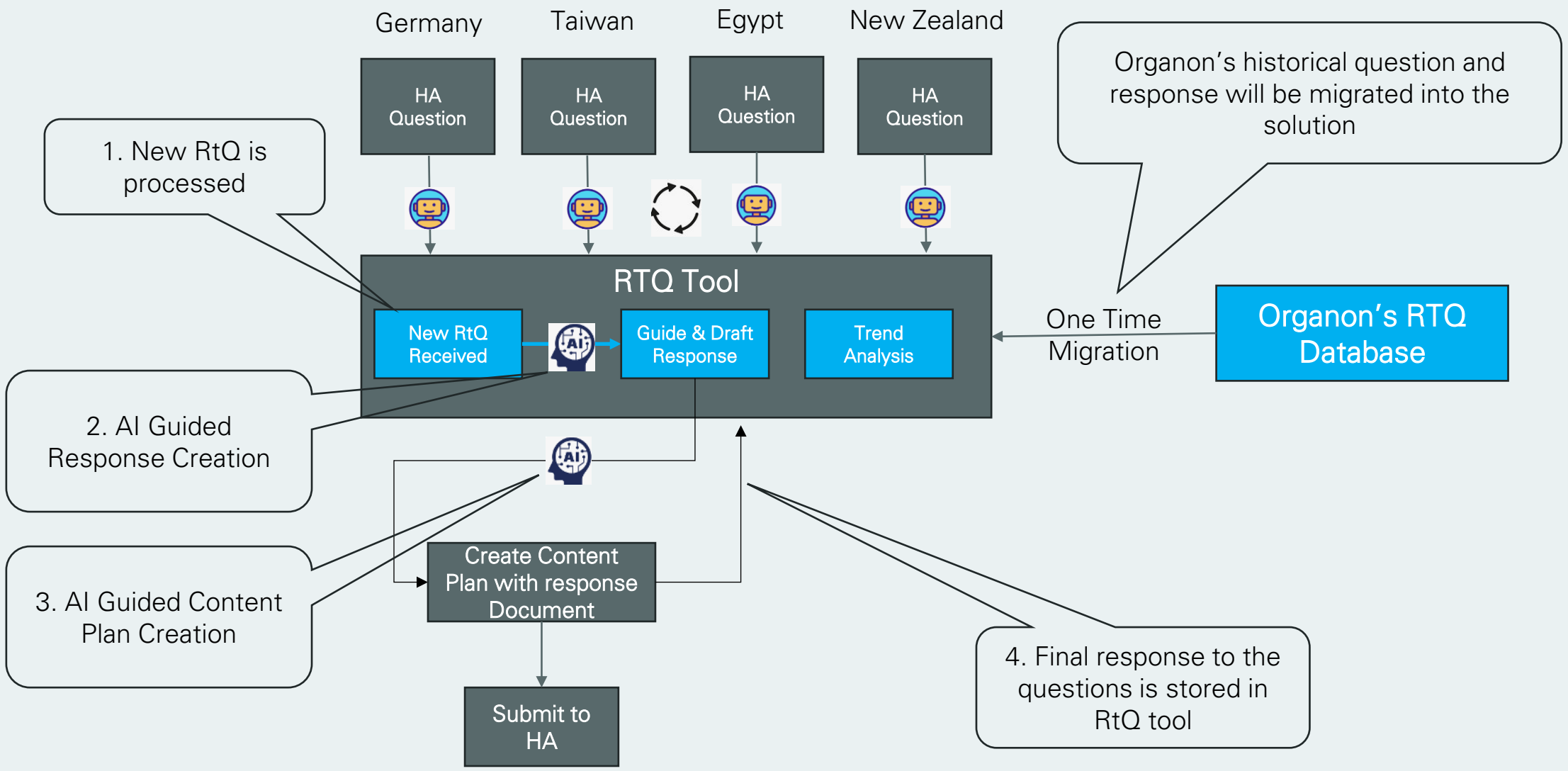
Ennov Advantage:

- AI is built within the platform (it is part of the Ennov ecosystem)
- Already Licensed
- Leverage what other companies requested
- Domain expertise lives in Ennov
- Will work with clients and prioritize AI roadmap (AI Lab)

Use Case 1: AI Assisted RtQ Solution

Business Problem	Key Features	Solution
• Large number of health authority questions are received annually, resulting in the preparation of many responses by regulatory affairs team. • RA need to review historical responses, trending and formulate a strategy for consistent response. • 100% manual effort.	• Ability formulate a draft response from historical product dossier and RtQ responses. • Ability to perform trending analysis of past RtQ based on historical data. • Ability to migrate Organon's RtQ database into a new solution.	• Automatic Parsing and analysis of HA questions. • Automate the initial draft of RtQ response. • Capture Q&A in a structured database. • Trending Analysis Reports

AI Assisted RTQ



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Use Case 2: Regulatory Intelligence

Business Problem	Solution
• Organon's Country RA conduct surveillance and assessment on their local regulatory intelligence information. • This is a time-consuming exercise by manually monitor HA websites for changes. • Information is manually entered in a workflow and database system.	• BoT or ChatGPT that automatically monitoring HA sites for relevant information. • Notify Country RA of any changes. • RA manually captures the change into regulatory intelligence database (with some level of review approval process) • Regulatory intelligence data can be used to drive regulatory activities.

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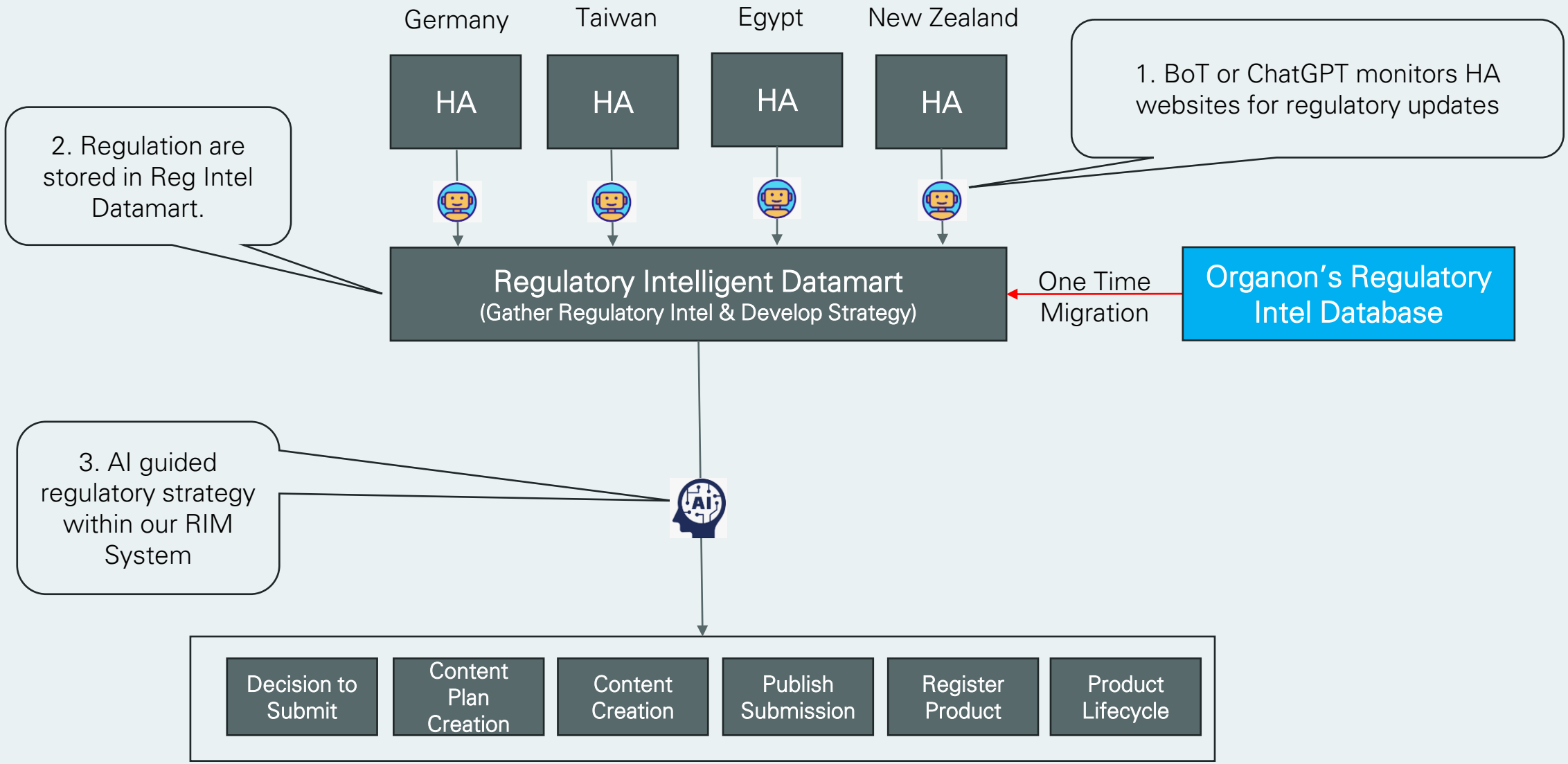
Regulatory Intelligence



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Use Case 3: ChatGPT and Agentic AI trained to support Ex US filings of our legacy products. These aren't just standalone tools, they work together to provide efficiency and free up resource to focus on top-line portfolio.

GPT Agent Framework for Regulatory Affairs

Me: I need the original market application and approval date for product GC-0987 in US

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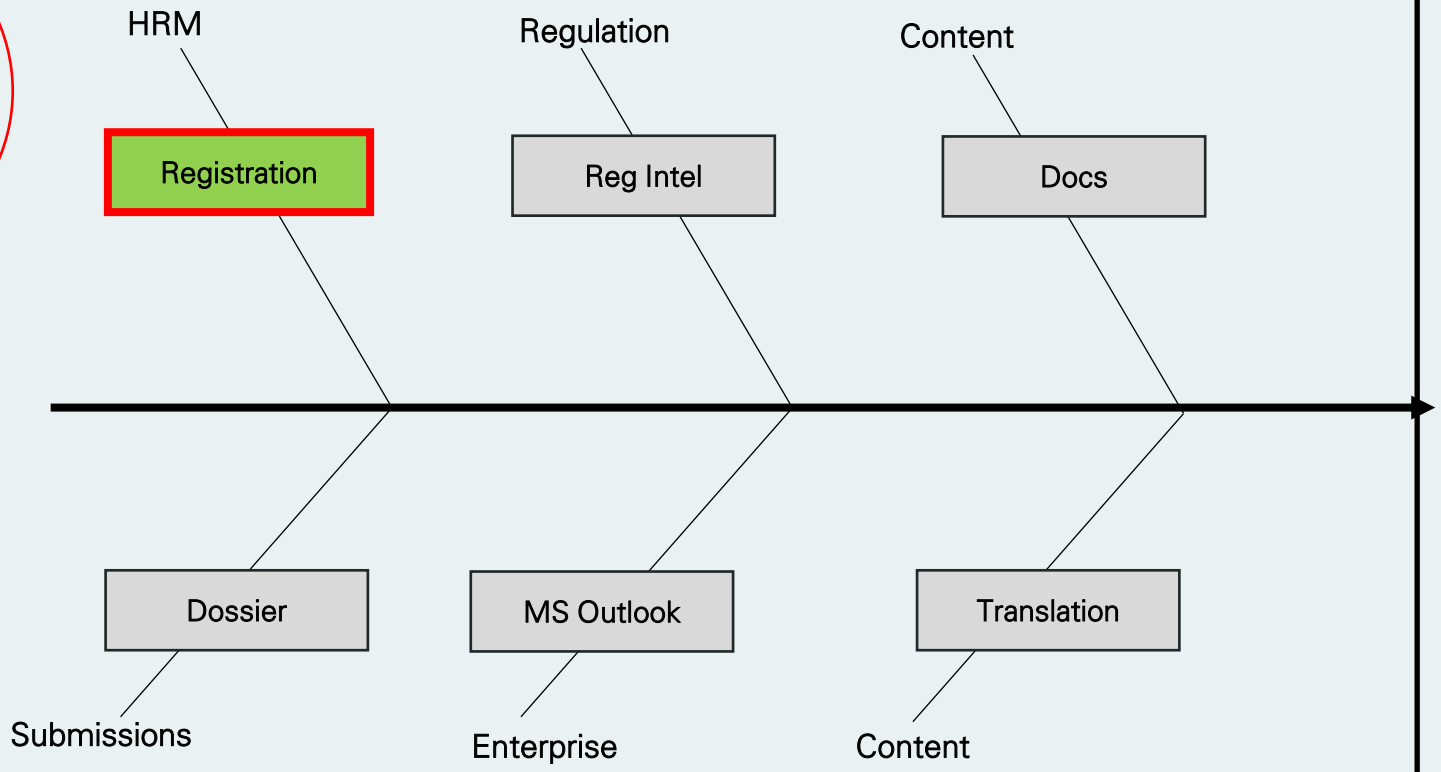
Tools



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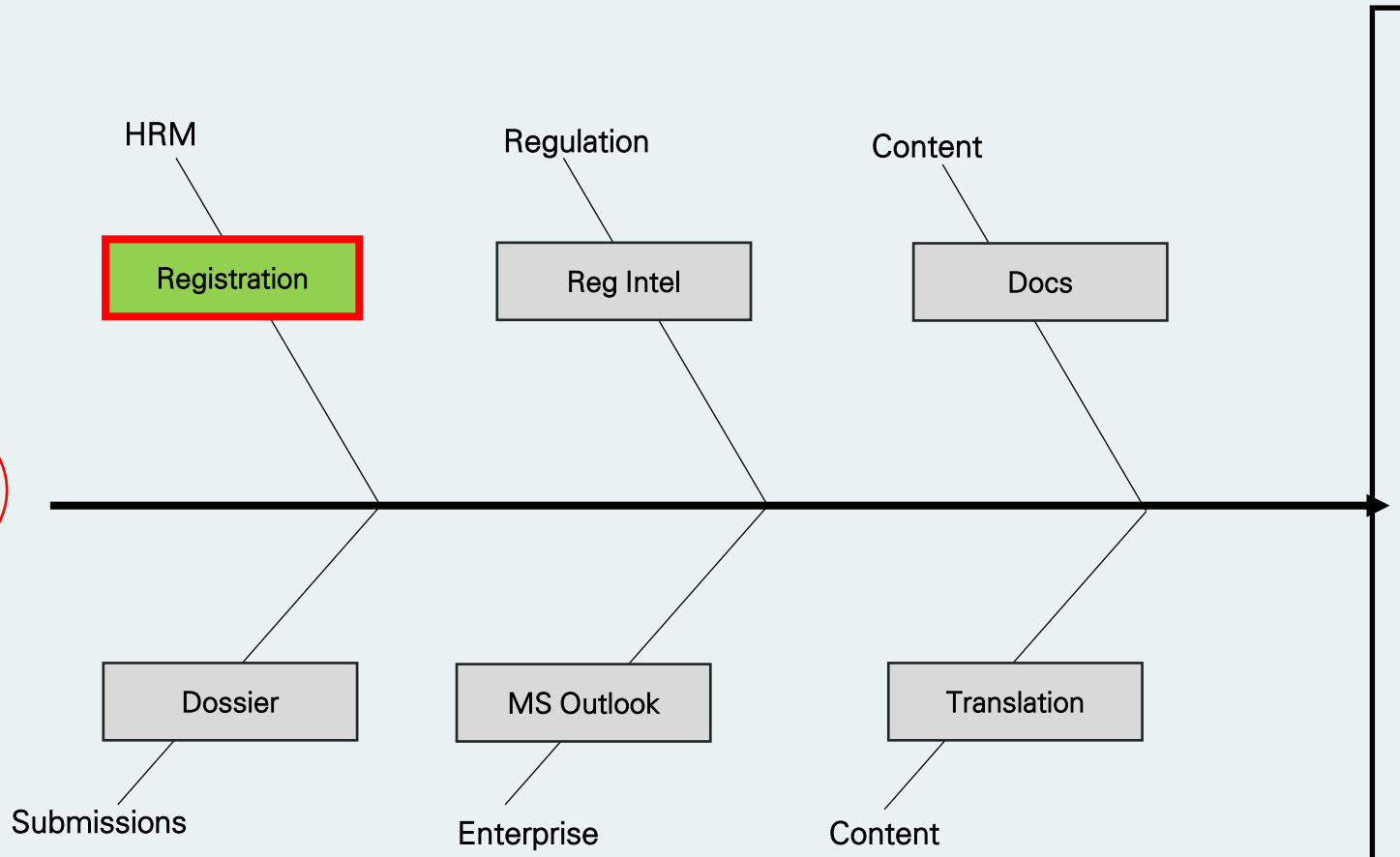

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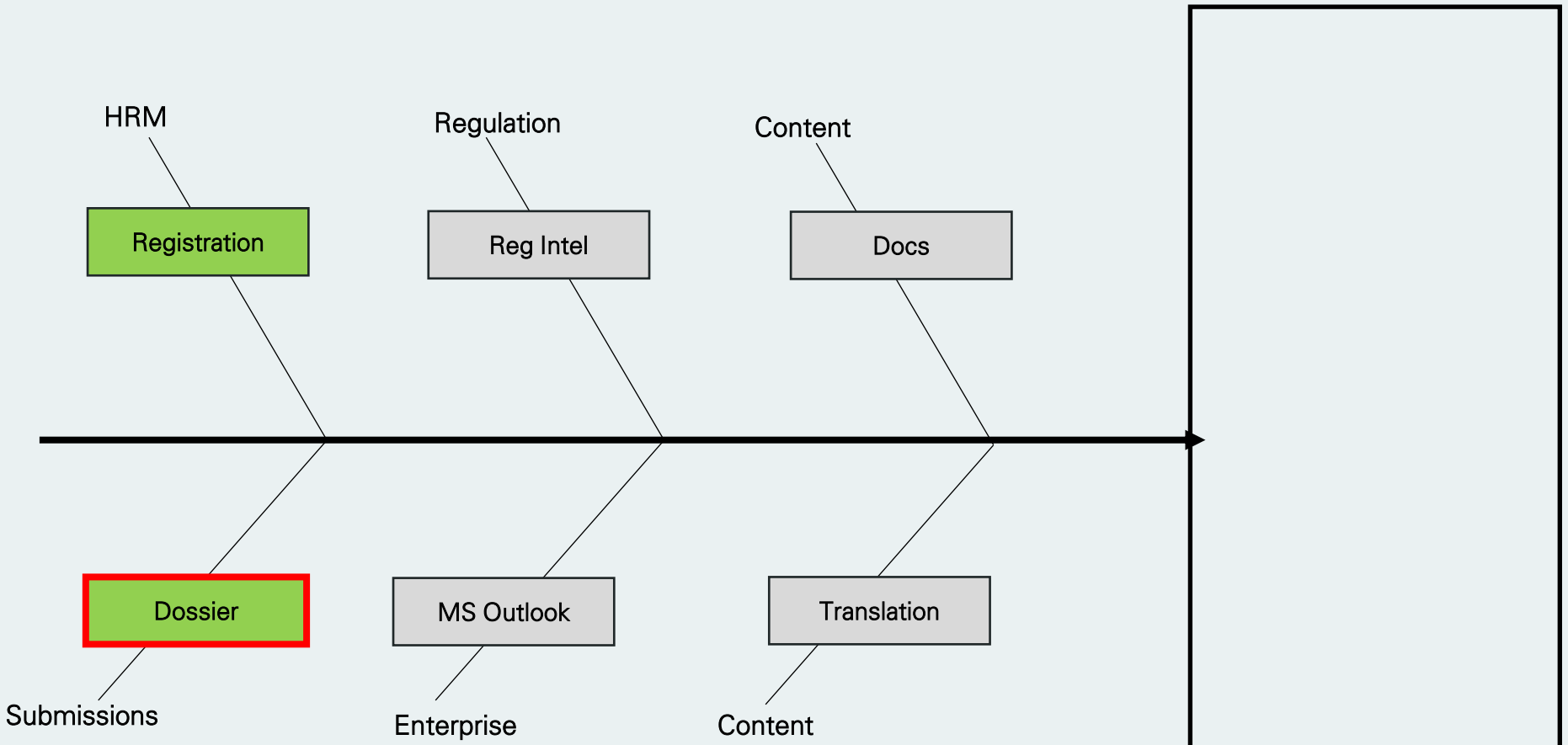

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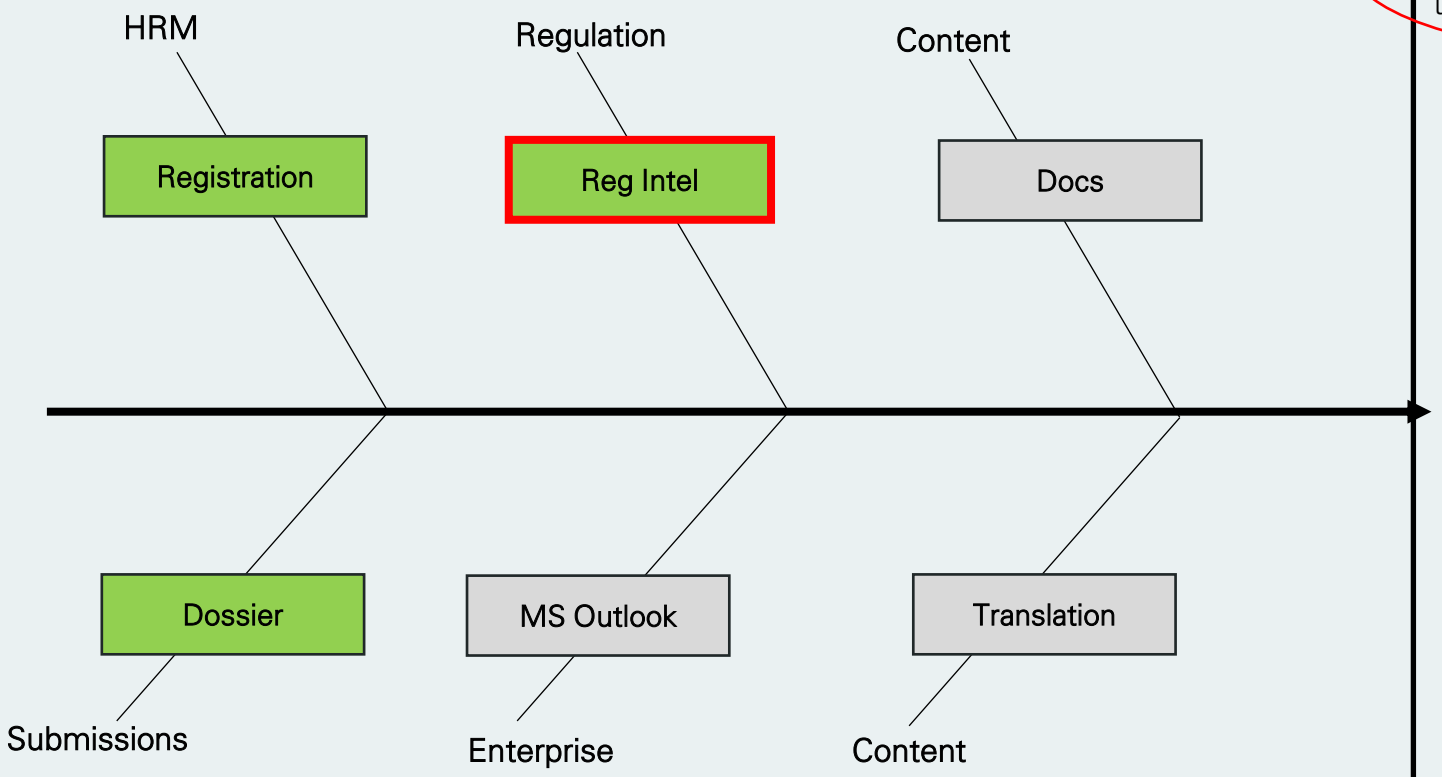

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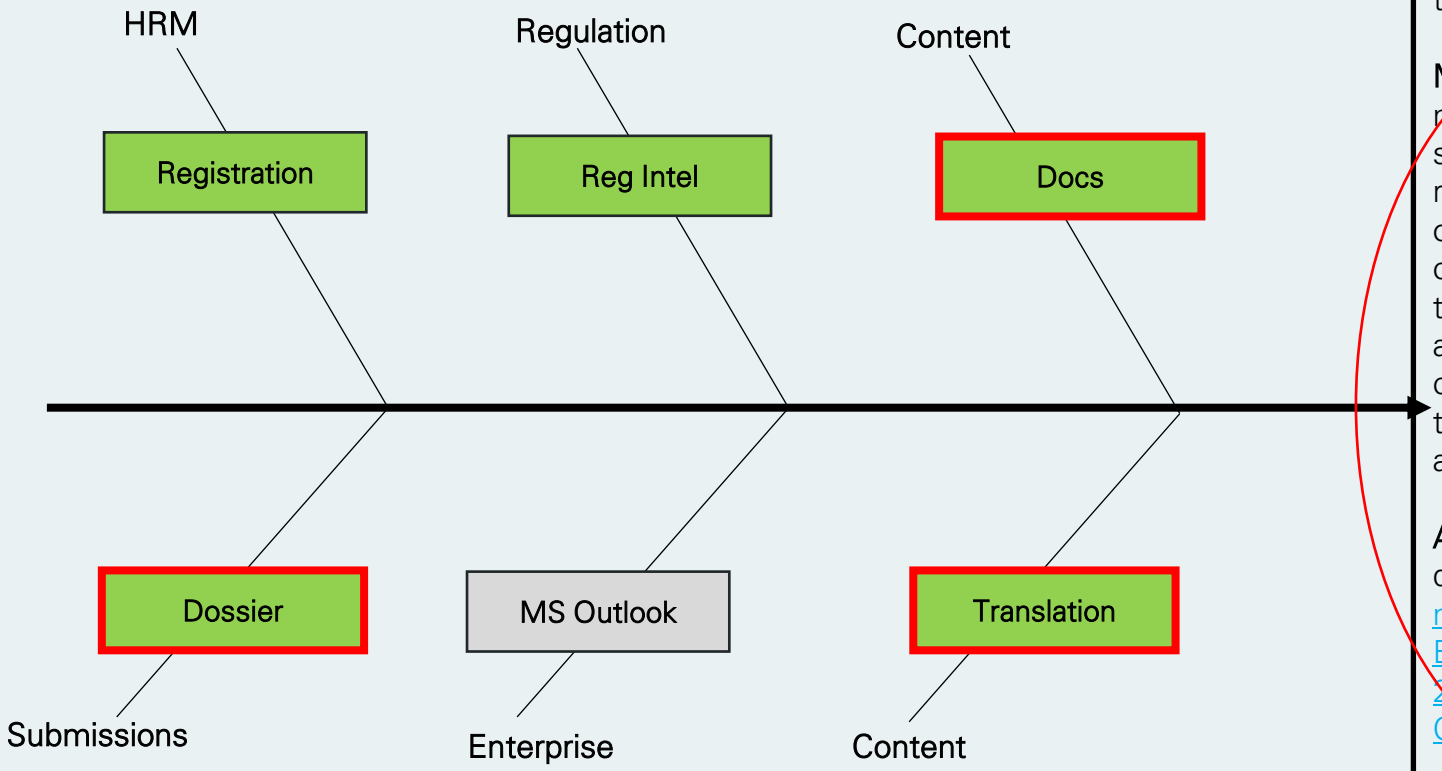

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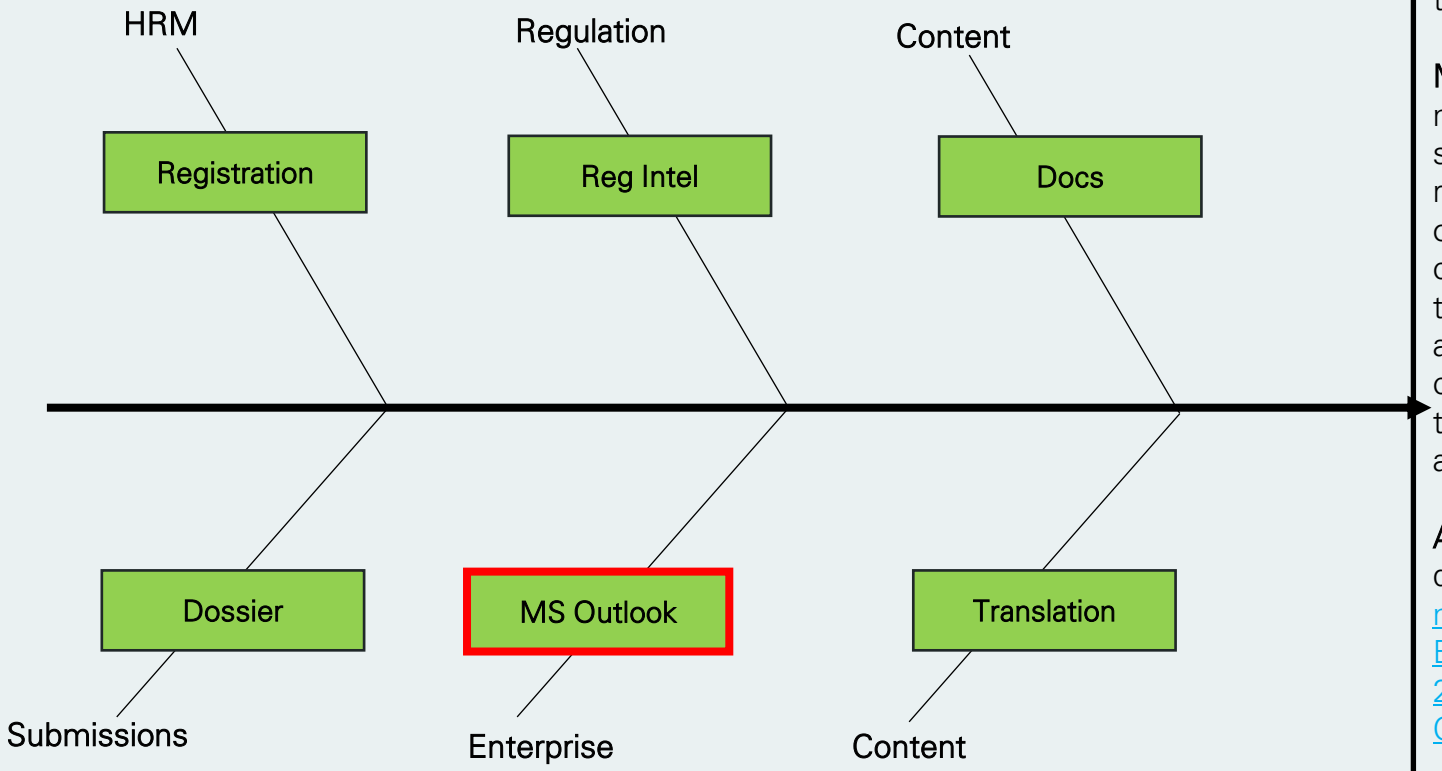

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AI: Email send

Tools

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Ennov’s AI Roadmap and Solutions

Q&A

Thank you