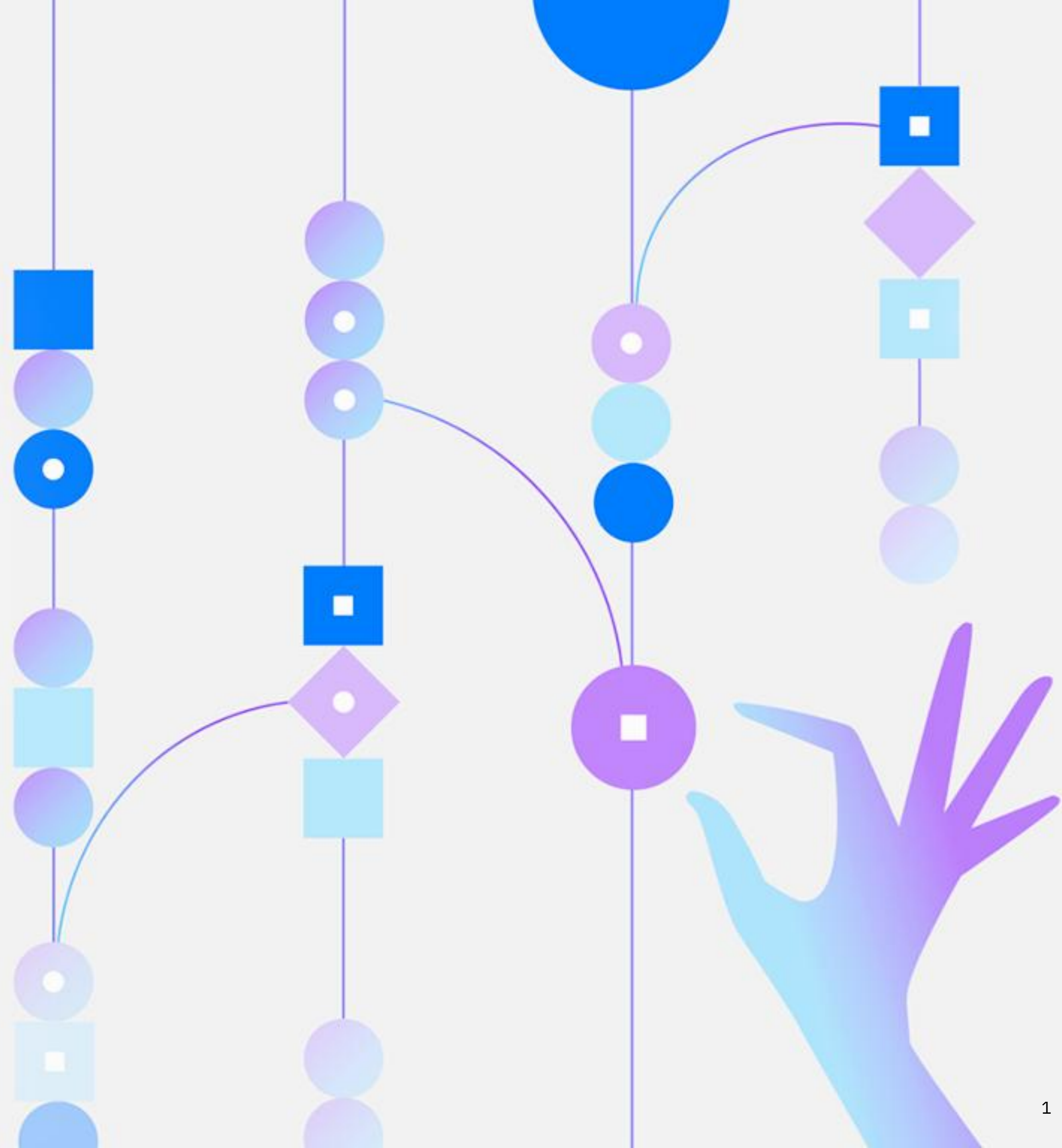




Regulate-**AI**

Automating Regulatory Reporting with Agentic AI

IBM Consulting, July 2025



The case for change in Regulatory Reporting

The Challenges | Hurdles in Regulatory Reporting and Compliance

Manual Drafting of Complex Reports



Highly skilled staff spend excessive time authoring lengthy and repetitive regulatory documents, resulting in high labor costs and long submission timelines.

Inconsistent Interpretation of Regulatory Guidelines



Subjective interpretation of evolving global regulations leads to inconsistencies across submissions, increasing the risk of non-compliance or rejection.

Multiple Data sources and distributed team



Data sources are wide ranging and large (spreadsheets, and legacy tools) — making it difficult to generate accurate, timely, and auditable reports. Requires resources with various skills and experience.

The Impact | High Cost, Slower Authoring, Delayed Revenue

\$12M Annual Reporting Costs

High Operational Spend

Driven by labor-intensive authoring processes across regulatory affairs and medical writing teams.

6+ Months to finalize submission

Manual drafting and fragmented review

Cycles delay time-to-market, resulting in lost revenue opportunities.



Increased Compliance Risk

Inconsistent documentation and manual errors can expose organizations to regulatory rejections, remediation efforts, and reputational damage.

The Need | Transforming regulatory reporting from costly bottleneck to AI assisted authoring

1 Supercharge report generation

Agentic AI can automate report structure understanding; accelerate content generation utilizing data from various sources, agents to check for accuracy and completeness, and keeping human in the loop and evolve with human feedback.

Value: Reduce cycle time for first draft from weeks to hours.

2 Continuous Learning

AI agents evolve over time with help from human feedback and ML based prompt tuning, making the AI system more and more efficient over time.

Value: Improve submission quality and reduce regulatory rework.

3 Scale for features, report types, content types and enterprise governance

Intelligent agents handle multimodal data, support integrations to systems and provide needed governance / guardrails

Value: Boost efficiency, Improve quality, Build confidence



Regulate-**AI**

Agentic AI to accelerate and scale your regulatory report authoring

IBM’s Agentic AI solution for regulatory report authoring simplifies draft generation in a more intelligent, traceable, and user-centric way

App Overview

Regulate-AI can supercharge regulatory report generation across life sciences, banking, ESG, and other compliance or legal reporting.

Uses an advanced agentic AI approach to understand patterns, content dept and requirements using sample reports.
Can connect to variety of data sources and generates an accurate and complete first draft. Works with human agent in the loop to evolved the draft in real time.

Allows user and admins to configure report types, samples, data sources, context for agents and many other parameters to provide comprehensive yet easy to set use setup.

Use Cases

- CTD & Regulatory Submissions
- Regulatory Financial Disclosures
- ESG & Sustainability Filings
- Risk & Compliance Reports (AML)

Capabilities



Agentic AI for Accuracy and Completeness

Advanced agentic AI for almost every aspect, training to generation and human in the loop approach to make it super easy and effective.



Meta Learning capabilities

to scale to alternative regulatory submission reports leverage training data and/or templates



Simple and flexible UI

Drag and drop, Multimodal support, integration with Microsoft word.



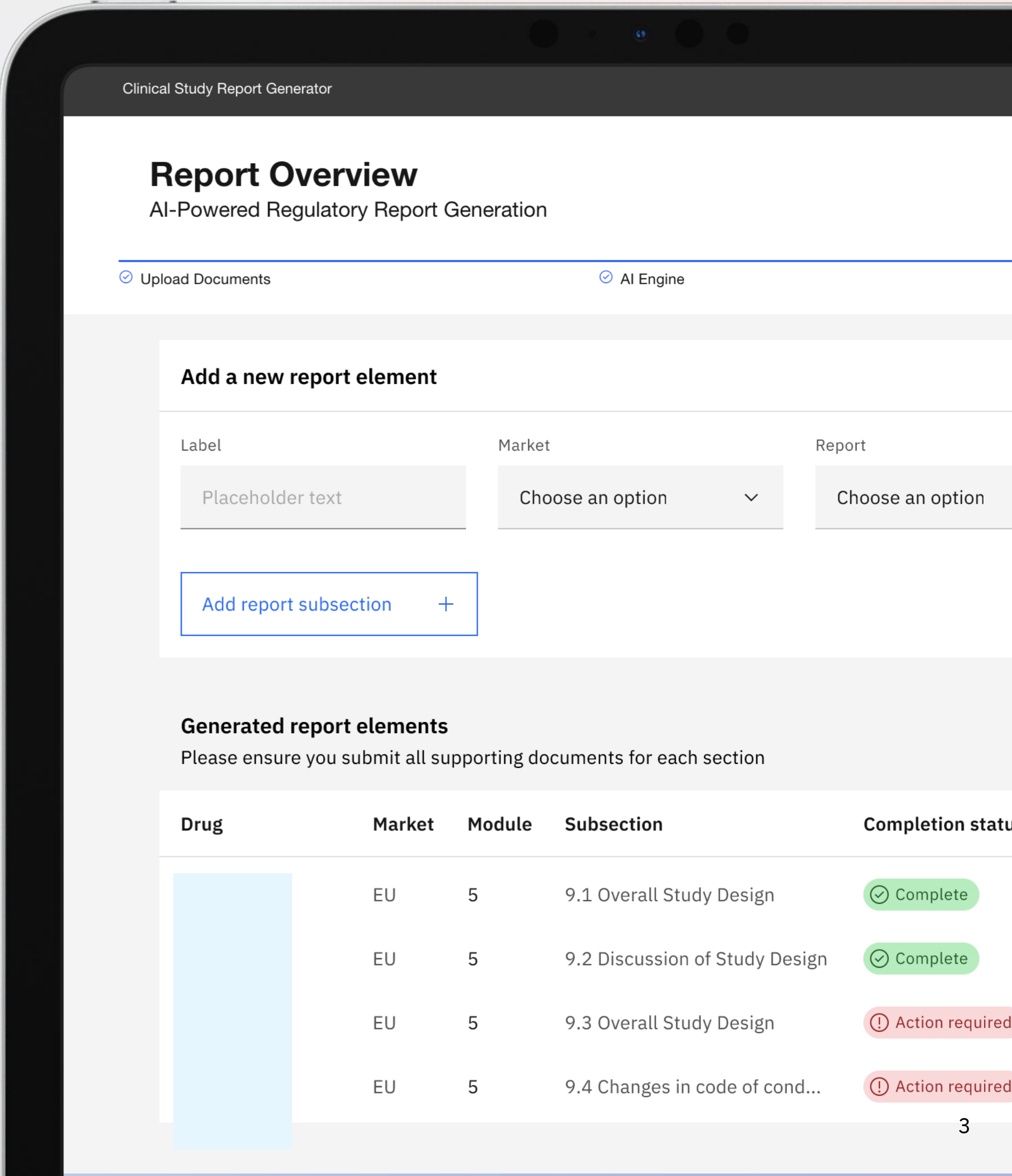
Customizability

Tailors to your formats, vocabularies, data source, context and workflows



Transparency and monitoring

Enterprise-ready with audit trails, access control, and compliance alignment (e.g., GxP, SOX, SFDR)





Regulate-**AI**

Personas, Process Flow and Business Value

Regulate-AI automates regulatory authoring, accelerating submission timelines, improving compliance, and reducing cost, with auditability and oversight.

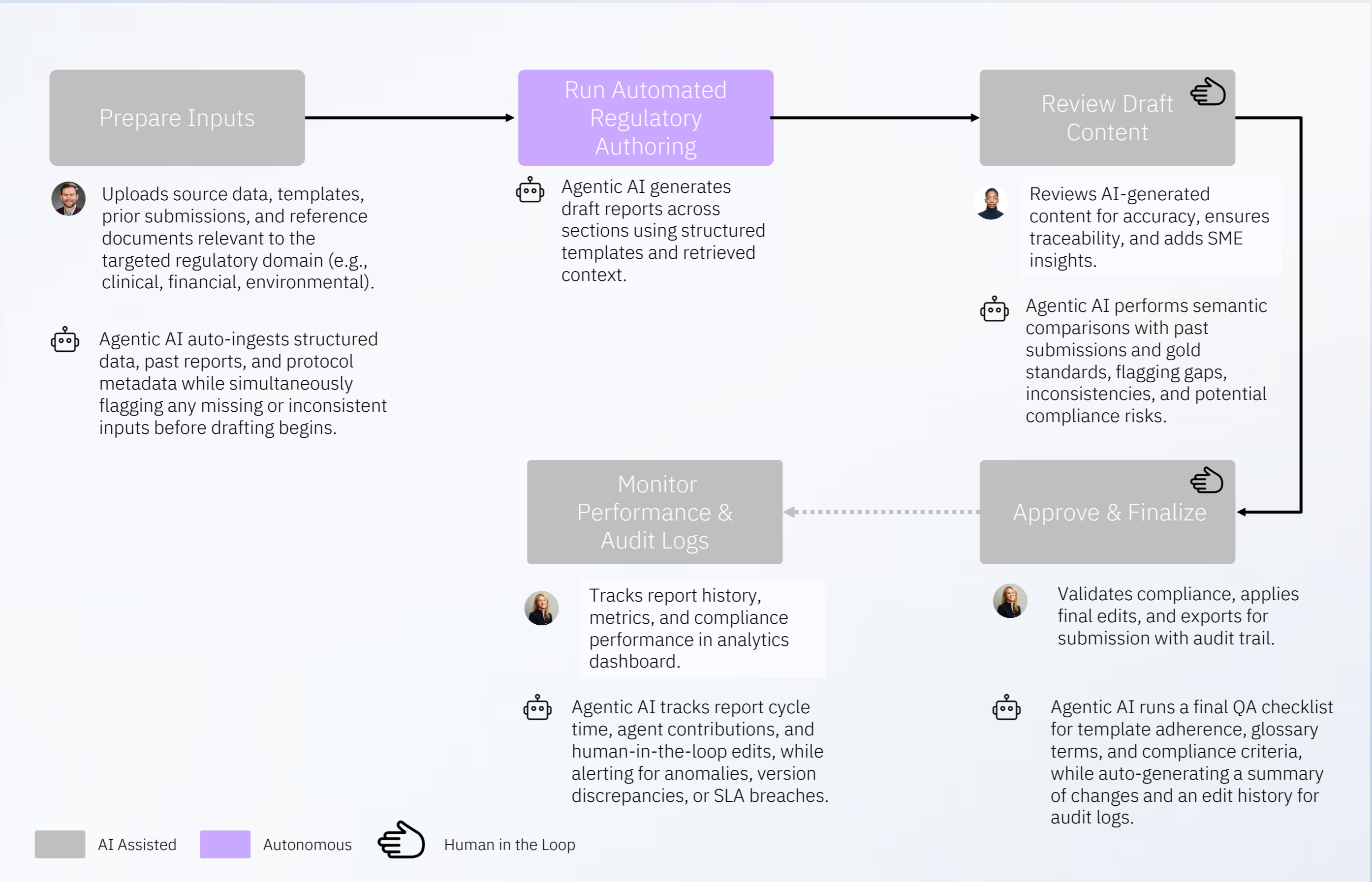
Personas

Elena
Regulatory Affairs Specialist

Marcus
Submissions Lead

Nia
Document Quality Reviewer

Workflow



Benefits & Value

>70%

Reduction in time and cost of authoring

80%

Decrease in manual effort and reviewer burden

90%+

Semantic match to gold-standard human-written reports

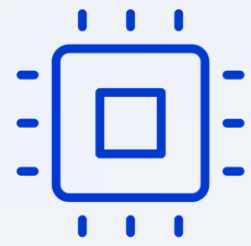
Accelerate Submissions
Generate high-quality content, saving months of effort and time to submission.

Strengthen Compliance
Ensure consistency, traceability, and GxP audit readiness

Scale Efficiently
Author across multiple products, reports, and geographies with reusable agents

* This journey is illustrative, and will vary based on the client's specific requirement

Features and Innovations



High Quality Reports

- High-Quality Output Generation (+90% overlap with human reports)
- Fact-checking for correctness & completeness)
- Chatbot and manual edit options



Transparency and Compliance

- Regulatory Grounding of LLMs
- **Full transparency** and traceability of AI via Chat
- Human-in-the-loop process
- Approach can be GxP approved



Scalable for various report types

- **Meta-Learning** capabilities to scale to alternative regulatory submission reports
- Leverage training data and/or templates



Governance and Compliance

- Enterprise-grade login and authentication
- Access controls
- Cloud-native integration & Security
- Monitoring and logs



Easy to use

- Simple drag & drop functionality
- Multi-modal inputs and outputs including text and tables
- Integration with Microsoft Word and Veeva

Agentic App in Action: Transformation of Regulatory Reporting for New Drug Applications

Problem



Labor Intensive, Manual, Prone to Error

Regulatory Submissions face several bottlenecks due to labor-intensive activities relating to Reg module and internal report writing, requiring skilled professionals and extended timeframes.



Inconsistencies And Substandard Quality

This manual, poorly controlled process is prone to report quality conformance and inconsistencies which ultimately delay and even put at risk the timely approval of a new drug applications



Solution

An Agentic App that uses multiple agents to generate the content required for the Report Submission and make it available for final review to a Medical Engineer through an Assistant



90%

Semantic coverage of generated content

95%

Accuracy of generated content

From 8 to 2 months






Faster Submission Filings and
Shorter Times to market through I
improved rates of approvability

From 6 weeks to 8 min

to generate first draft

5 Key Features

Regulate-AI delivers features designed to accelerate regulatory content creation, improve quality, and ensure compliance — across industries from life sciences to financial services and sustainability

-  Multi-Agent Orchestration for Authoring
-  Semantic Alignment and Traceability
-  Authoring Timeline & Submission Tracker
-  Learn from sample reports and templates.
-  Human in the loop feedback and improvement over time.

Clinical Study Report Generator

Report Overview

AI-Powered Regulatory Report Generation

Upload Documents

AI Engine

Draft Generation

Add a new report element

Label

Placeholder text

Market

Choose an option

Report

Choose an option

(Sub-)section

Choose an option

Add report subsection

+

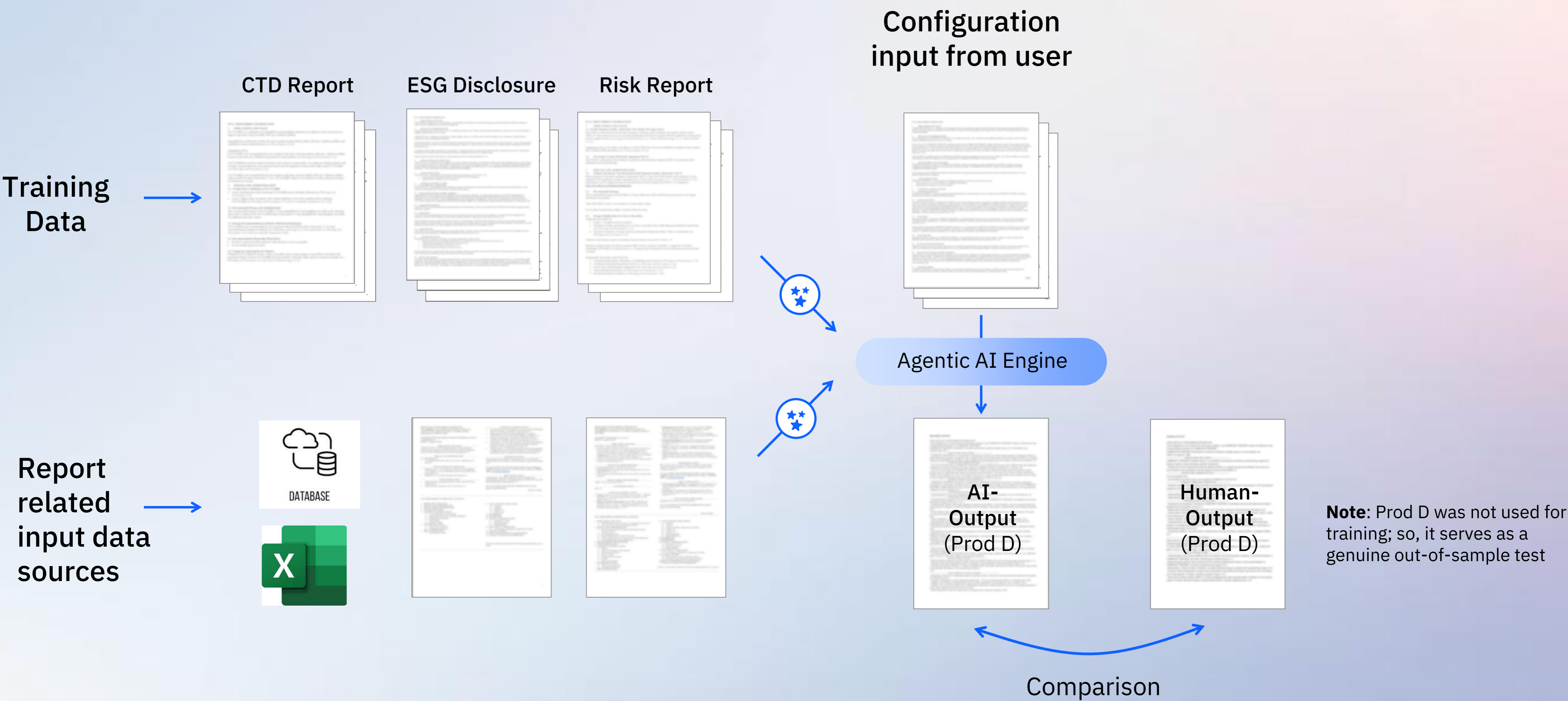
Generated report elements

Please ensure you submit all supporting documents for each section

Drug	Market	Module	Subsection	Completion status	Actions
Lanreotide	EU	5	9.1 Overall Study Design	Complete	View documents
Lanreotide	EU	5	9.2 Discussion of Study Design	Complete	View documents
Lanreotide	EU	5	9.3 Overall Study Design	Action required	Upload documents
Lanreotide	EU	5	9.4 Overall Study Design	Action required	Upload documents

Scalability of Reguate-AI: New Report Types

Regylate-AI is buit to with scale in mind to cater to different content types and content generation use-cases



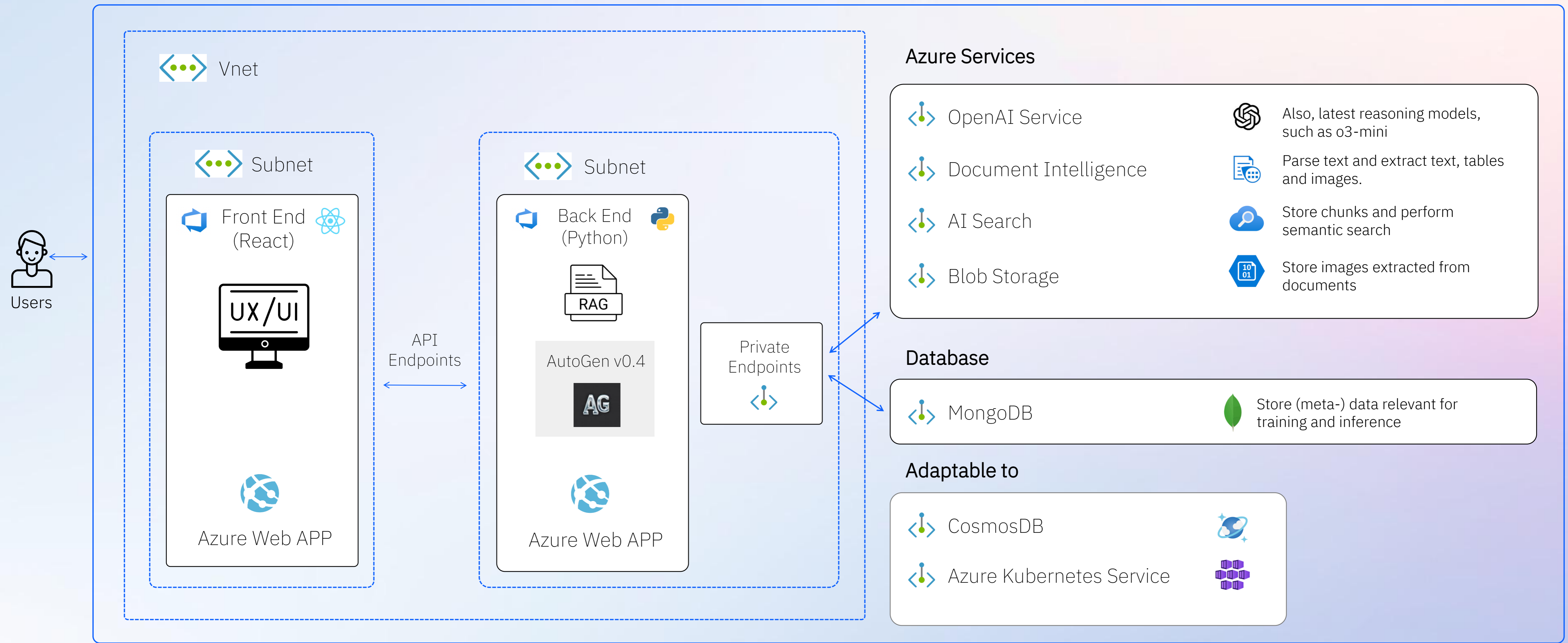
Agentic AI Regulatory Reporting

presented by

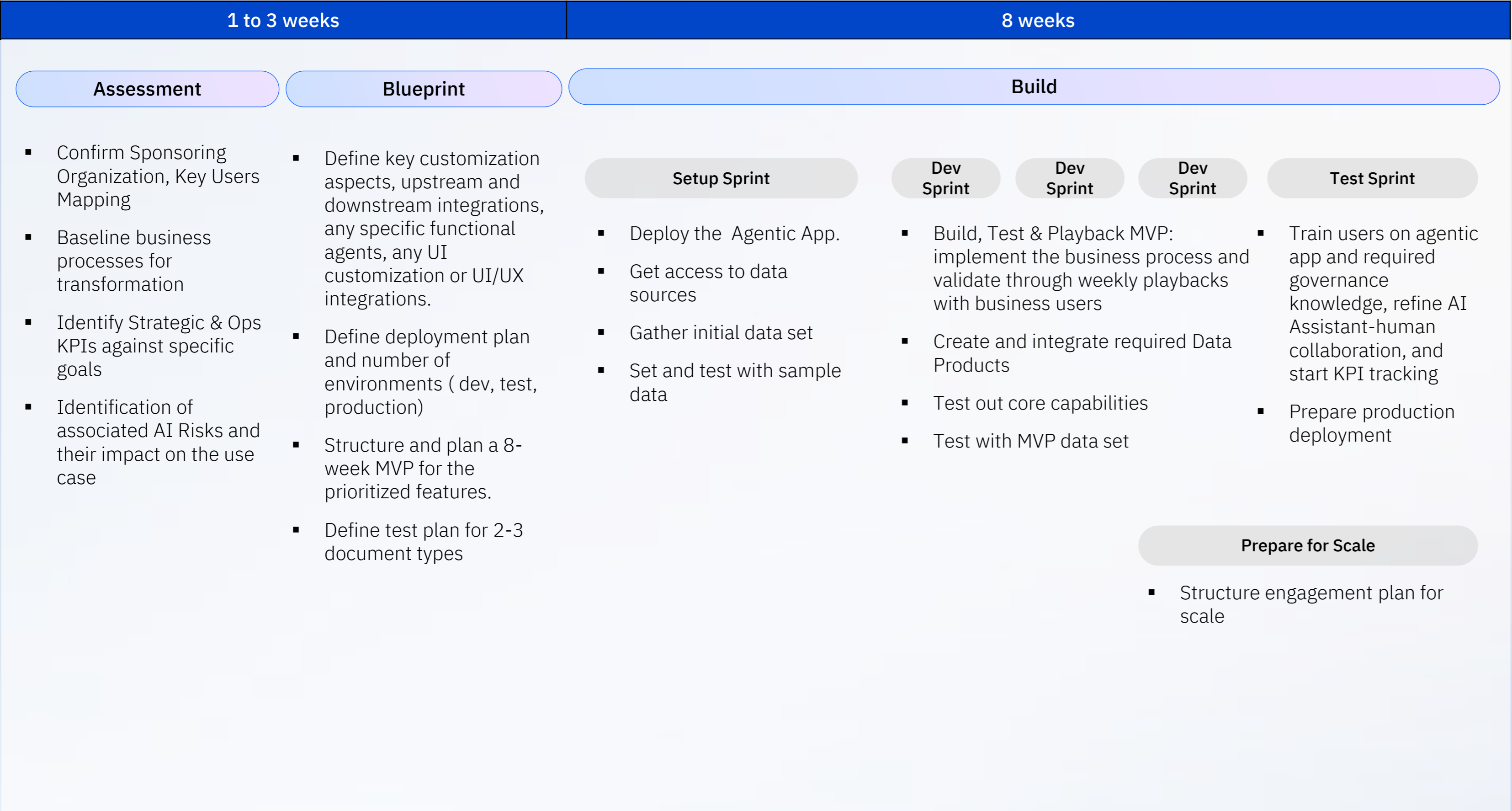
IBM Consulting

AI Integration Services, Global Offerings

Regulate-AI Solution Architecture



Indicative Delivery Timeline



GenAI Assistants, Tools, Assets

- Agentic AI Readiness Score Framework
- ICA Assistant to classify process activities
- Mapping process mining metrics to Agentic AI Readiness Scores.

- ICA Assistant to generate first mapping to agentic architecture
- Agentic app Reference architecture

- Base App deployment code and containers
- GIT Repos
- Documentation and Deployment Guide

Delivery Squad

- Delivery Executive
 - Agentic AI technical Lead
 - Technical Architect
 - UX Designer
 - Data Scientist
- AI Engineer
 - Full Stack Developer
 - DevOps
 - Test Specialist

Assumptions and Dependencies

- 1

Setup and onboarding:
Environment access prior to project kickoff
 - Asset will be deployed in one development environment and availability zone
 - Azure resources provisioned
 - Required knowledge store finalized

IBM development team onboarded to environment within first week of project
- 2

SME time commitment:
SME input needed:
 - Data set knowledge
 - As is process and expected results
 - UI validation

SME feedback within three (3) business days
- 3

Base deployment:
 - Will cover core base features of the app within 8-10 week MVP
 - Following query types will need additional development effort
 - Tool integration like raising ticket in workflow tool like service or any other type of integration with external API
 - Hyper personalization by connecting to user data
 - Queries based structured data sources like data base
 - Complex queries which require custom calculation before responding to user question

Get in touch and find out more



Regulate-**AI**

Find out more and request
a demo in ICA4AA Agentic
App Library

[Click here](#)



Read more about the
technical documentation in
our GitHub

[Click here](#)



Visit AI Integration Services
space on Content+

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