

POSEIDON

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Agenda

- Business Goal
- Core Functionalities
- Defined KPIs and results
- Functional Building Blocks
- Challenges
- Platform interface



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Business Goal

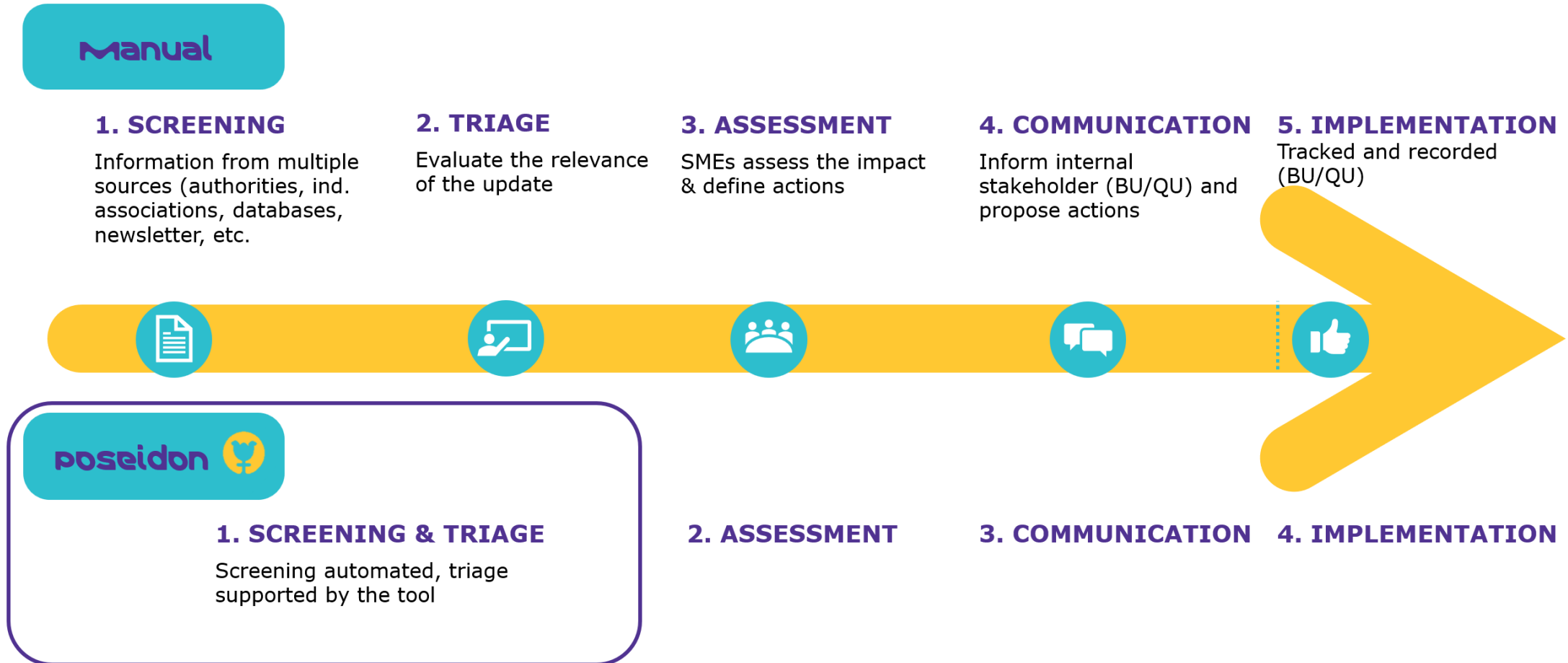
**Develop an AI/ML system
able of screening regulatory/safety
news from HA's websites**

To enhance the efficiency and effectiveness of screening activities, to be more sustainable, streamline regulatory compliance and provide an extended assessment of regulatory impact.



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Move from manual to semi-automated process



Core functionalities & cross-functional usability

Definition of core functionalities

- Retrieving data from HA websites
- Information Screening
- Triage (Prioritization) including version and duplicates handling

Definition of flexibility for usability

- Adaptability for Screening (Relevance) and Triage (Priority)
- Scalability for other use cases

Future functionalities

- Documents comparison
- Summary creation
- Translation
- Alert generation
- Chat functionality





COMPETITIVE ADVANTAGE THROUGH INNOVATION



First-mover advantage

Competitor analysis confirms no existing solutions in the market matching Merck's business scope of screening customized to our processes



Strategic alignment

- ✓ Supports **digital transformation** objectives
- ✓ **Enhances organizational capability** in regulatory intelligence

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Risk Mitigation & Compliance Excellence

Reduce Potential Compliance Exposure

- Current **manual screening cannot guarantee full coverage** of regulatory news. Poseidon strengthens through **systematic, automated monitoring**
- Supports highly **proactive** regulatory risk management

Operational Efficiency

- Eliminates waste through function-specific, **refined outputs**
- **Reduces manual effort** while improving accuracy and coverage
- Machine learning capabilities ensure **continuous improvement** through user feedback

Scalable Business Impact

- **Built for enterprise scalability:** System designed to rapidly incorporate additional business functions
- **Cross-functional collaboration opportunities** in regulatory requirement assessment
- **Future-ready architecture** adaptable to new business logics and evolving HA website structures



POSEIDON IS NOT JUST A TOOL



As a strategic capability POSEIDON

- ✓ *drives competitive advantage*
- ✓ *operational excellence and*
- ✓ *organizational transformation*

POSEIDON Proof of Concept

Defined KPIs

KPI	Applicability	Definition	Target
Coverage	KPI on scraper functionalities	N° of Health Authorities scraped (html and pdf formats)	2 Health Authorities linked to Poseidon
Speed	KPI on scraper functionalities	Time to fetch new document from source into Poseidon	Less than 8 hours (overnight)
Recall	KPI on screening quality	Proportion of documents scraped and classified as relevant by Poseidon	60%
Precision	KPI on screening quality	Proportion of documents classified as relevant are correctly relevant (matching manual selection)	50%
User Interface	Qualitative KPI on usability	After an introduction and some practice, how long does it take an SME to screen and score a document	Positive feedback



POSEIDON Proof of Concept - Evaluation

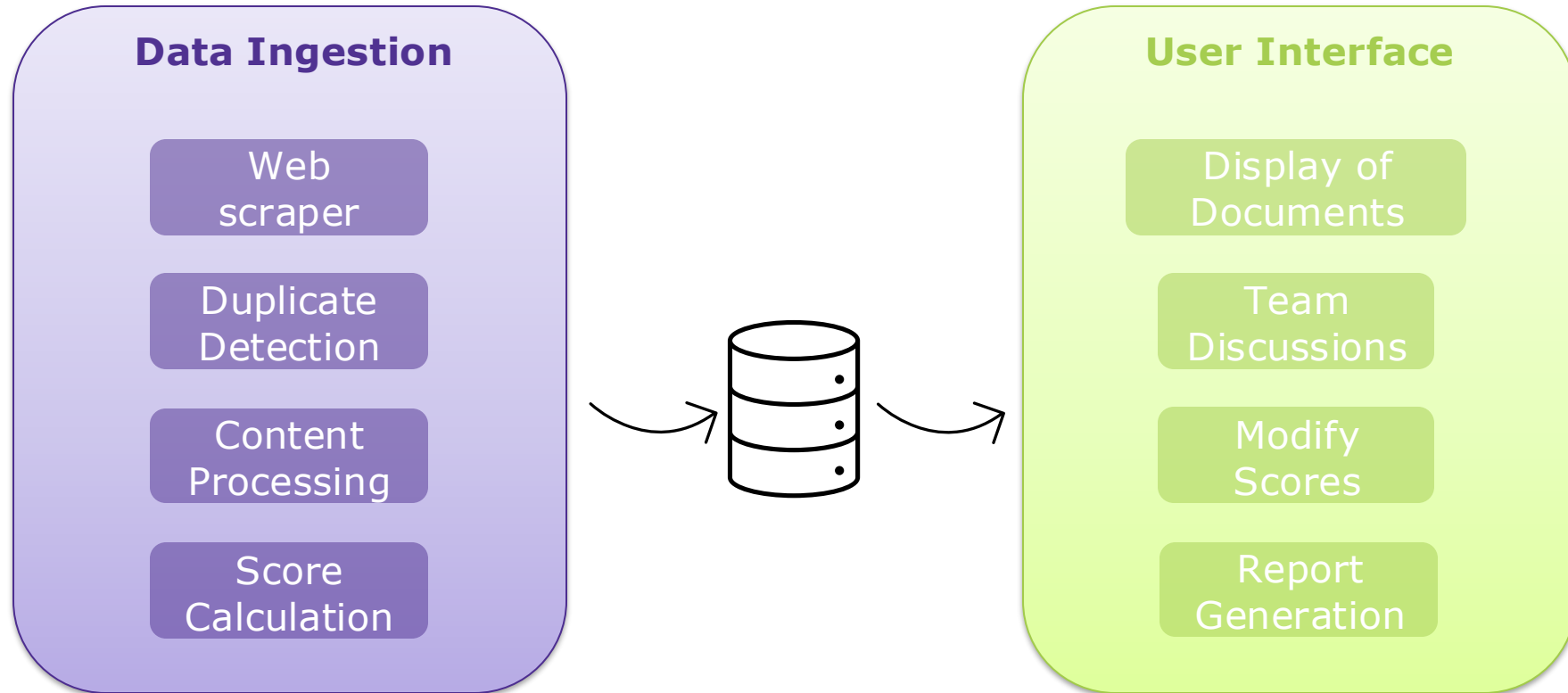
KPIs results

Profile	Coverage	Speed	Recall	Precision	User Interface
Definition	N° of Health Authorities scraped (html and pdf formats)	Time to fetch new document from source into Poseidon	Proportion of documents scraped and classified as relevant by Poseidon	Proportion of documents classified as relevant are correctly relevant (matching manual selection)	After an introduction and some practice, how long does it take an SME to screen and score a document
Business function 1	<i>EMA, CHMP, CMDH</i>	<2h	80%	70%	Positive feedback
Business function 2	<i>EMA, FDA, EC, MHRA, Health Canada, ICH, PIC/S, and EDQM</i>	<2h	70%	30%	Positive feedback



POSEIDON Architecture

Functional Building Blocks



POSEIDON Technical Workflow

Data Ingestion

Web Scraping

- System looks at defined entry pages
- Detects, downloads and stores new documents

Conversion

- Converts documents from various formats into text files
- Removes formatting artifacts

Embedding

- Creates unique vector per document
- Vector is used for document comparison and duplicate detection

Processing

- *Triage* applies business rules to documents
- Calculates scores
- Infers labels
- Categorizes documents



POSEIDON Scoring Algorithms

Triage

1 Keyword Search

- Interpretable, easy to implement
- Good for product names

2 Large Language Models

- Can provide an explanation for the result
- Understands context
- Requires careful prompt engineering

3 Decision Trees

- Classical ML approach
- Performs well with sufficient and meaningful data
- Allows for improvement over time

4 Other Classifiers

- Neural Networks
- Support Vector Machines
- And others...



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Challenges

Definition of Duplicate

Definition of a duplicate is ambiguous and depends on the context.

Long Documents

Long documents might not fit into context windows of LLMs.
Long documents might contain a large number of topics.

Risk of Missing Relevant Documents

How high is the confidence in the ML model?

Varying Requirements

Build one system to serve all business units.



POSEIDON Interface

Dashboard



Document Dashboard - CMC

All documents

new

ready for review

reviewed

rejected

Status	Title	URL	URL...	Published	Last Modified	Keywords	Action
new	Class 2 Medicines Recall: Paracetamol 500mg Tablets, ...	https://www.gov.uk/drug-device-aler...	active	09/06/2025 10:01	10/07/2025 13:...	change	Open
new	Field Safety Notices: 2 to 6 June 2025	https://www.gov.uk/drug-device-aler...	active	10/06/2025 09:23	10/07/2025 13:...	change	Open
new	Class 4 Medicines Defect Notification: Dulcolax Adult 5 ...	https://www.gov.uk/drug-device-aler...	active	10/06/2025 09:59	10/07/2025 13:...	change	Open
new	MHRA Safety Roundup: May 2025	https://www.gov.uk/drug-device-aler...	active	13/06/2025 14:11	10/07/2025 13:...	change	Open
new	Agenda - PHEG sub-group on cancer (24 June 2025)	https://health.ec.europa.eu/latest-u...	active	16/06/2025 13:43	10/07/2025 13:...	Platform	Open
new	SCCS - Final Scientific Advice on Benzophenone-2 (BP-...	https://health.ec.europa.eu/latest-u...	active	30/06/2025 08:55	10/07/2025 13:...	Platform	Open
new	Implementation dialogue on Biocides (15 July 2025)	https://health.ec.europa.eu/events/i...	active	30/06/2025 13:33	10/07/2025 13:...	Animal welfare, Platform	Open
new	Stakeholders' Consultation on EudraLex Volume 4 - Goo...	https://health.ec.europa.eu/consulta...	active	07/07/2025 11:55	10/07/2025 13:...	GMP compliance, Innovat...	Open



POSEIDON Interface

Cross-Functional collaboration

DOCUMENT INFO

Status: 🔍 ready for review

Title: Requirements on Submissions for New Marketing Authorisation Applications within MRP, DCP and National Procedures

URL: <https://www.hma.eu//human-medicines/cmdh/procedural-guidance/esubmissions.html#c3063>

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THANK YOU!
QUESTIONS?



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