



Leveraging LLMs, and how it can be used to
Streamline Regulatory Submissions and Accelerate
Clinical Trial Approvals

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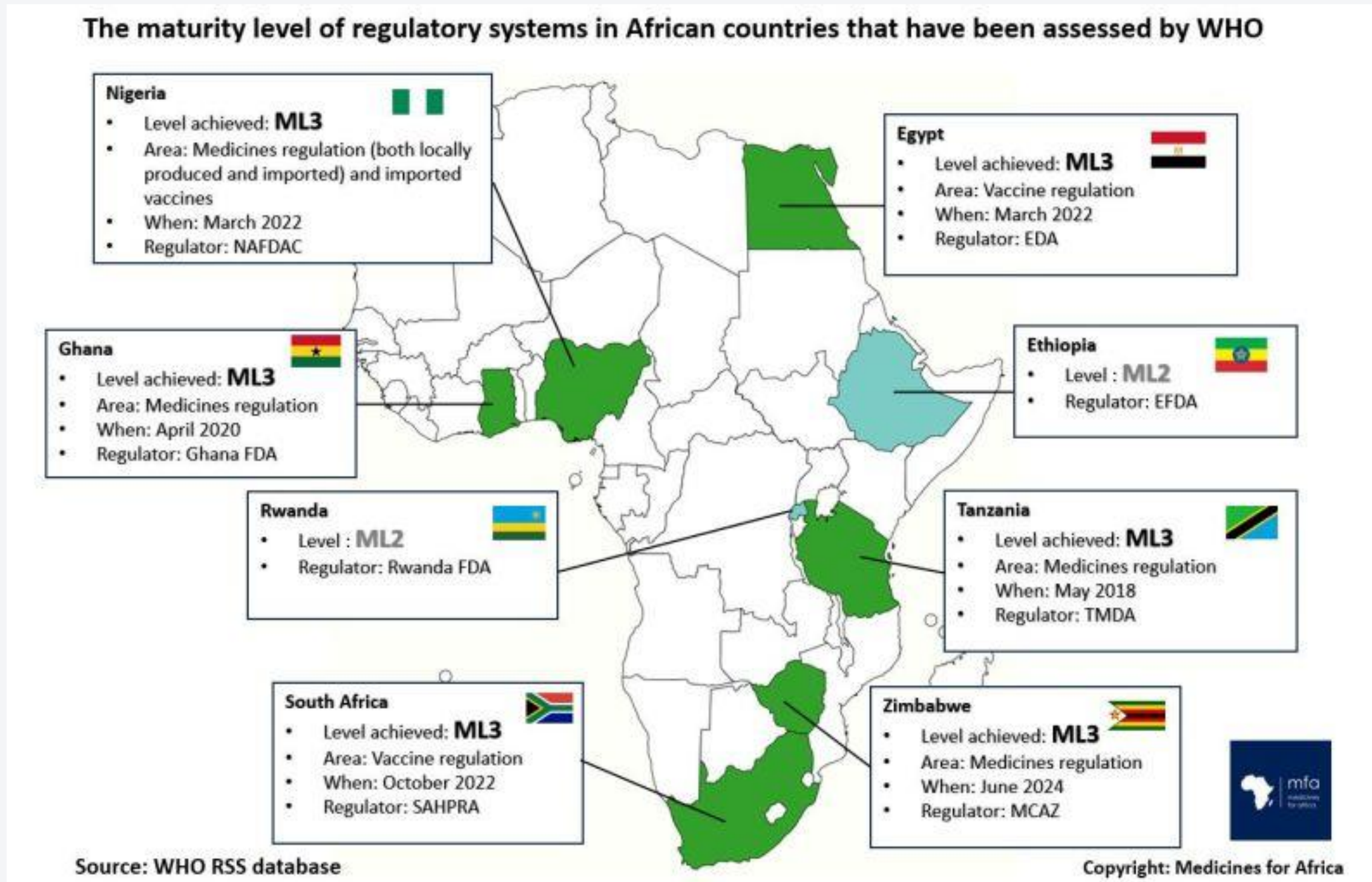
scigenix



AGENDA

- **Problem Statement:** How can we improve the turnaround times of NRAs in Africa?
- Large Language Models (LLMs) **101**
- The Deepseek Story  **deepseek**
- NRA Workflow Example: Registration of new Generic
- How LLMs can be used to Streamline this process

Problem Statement: How can we improve the turnaround times of NRAs in Africa?



Regulatory Landscape

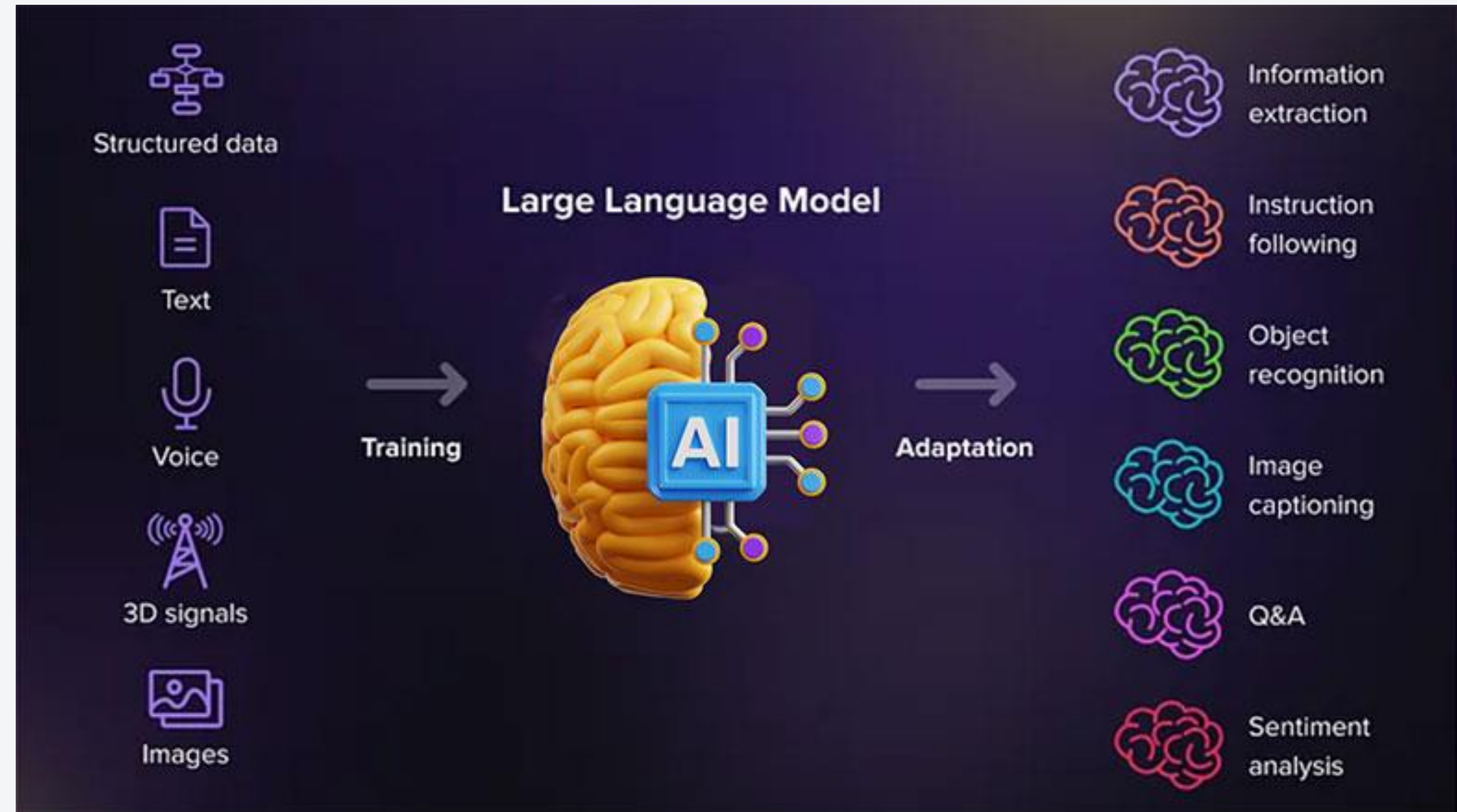
The Global Benchmarking Tool (GBT) represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems

01	National Regulatory System (RS)
02	Registration and Marketing Authorization (MA)
03	Vigilance (VI)
04	Market Surveillance and Control (MC).....
05	Licensing Establishments (LI)
06	Regulatory Inspection (RI).....
07	Laboratory Testing (LT)
08	Clinical Trials Oversight (CT).....
09	NRA Lot Release (LR).....

https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/list-of-nras-operating-at-ml3-and-ml4.pdf?sfvrsn=ee93064f_23&download=true

What is a Large Language Model (LLM) ?

A "large language model" (LLM) is essentially a very powerful computer program that has been trained on a massive amount of text data, allowing it to understand and generate human-like language, like writing paragraphs, answering questions, or translating languages, by recognizing patterns and connections within the text it has learned from; think of it as a super-smart AI that can "talk" and write like a person.



In simple terms: Imagine having a robot with amazing photographic memory where it can remember **EVERYTHING** it reads. It can learn new things at an **INCREDIBLE** speed. You can ask it to recall anything and also link certain elements together, but it has the logic ability of an 4 year old, so not very good with math, as an example.

The DeepSeek Story...



Reuters World Business Markets Sustainability Legal Breakingviews Technology Investigations

DeepSeek sparks AI stock selloff; Nvidia posts record market-cap loss

By Sinéad Carew, Amanda Cooper and Ankur Banerjee
January 28, 2025 2:31 AM GMT+2 · Updated 3 days ago

Summary Companies

- Tech stocks sink, Nvidia drops sharply
- China's DeepSeek AI assistance surges in popularity
- Nervous investors seek safe havens, dollar falls

NEW YORK/LONDON/SINGAPORE, Jan 27 (Reuters) - Global investors dumped tech stocks on Monday as they worried that the emergence of a low-cost Chinese artificial intelligence model would threaten the dominance of AI leaders like Nvidia (NVDA.O), evaporating \$593 billion of the chipmaker's market value, a record one-day loss for any company on Wall Street.

Forbes FORBES > BUSINESS

BREAKING

DeepSeek Panic Live Updates: Nvidia Stock Drops 4%—As Trump Reportedly Mulls China Chip Sale Restrictions

Derek Saul Forbes Staff
Derek Saul has covered markets for the Forbes news team since 2021.

Mary Whitfill Roeloffs Forbes Staff
Mary Roeloffs is a Forbes breaking news reporter covering pop culture.

Jan 29, 2025, 04:07pm EST

Updated Jan 29, 2025, 04:18pm EST

TOPLINE The release of a less capital-intensive artificial intelligence model from China's DeepSeek sent a chill through the U.S. stock market this week, headlined by losses Monday and Wednesday from Nvidia, the Silicon Valley giant which designs most of the pricey semiconductor technology powering the AI revolution.

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DeepSeek

Tech billionaires lost almost \$100bn in stock market selloff sparked by DeepSeek

Nvidia saw \$600bn of its market value disappear, while its CEO, Jensen Huang, saw his net worth drop by nearly \$21bn

- Explainer: what is DeepSeek and why did US tech stocks fall?
- James Vincent: DeepSeek panic reveals an AI world ready to blow
- Nils Pratley: the stock market is terrible at valuing tech revolutions

Nvidia CEO Jensen Huang was the big loser in Monday's tech-stock bloodbath. Photograph: Ann

Edward Helmore
Tue 28 Jan 2025 15:30 GMT

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- Was he grave, sombre, the consoled-in-chief? Are you kidding - this is Trump

What Happened?

- Nvidia is the World Leader in GPUs which is used to train LLMs
- They bring out new, faster and more expensive GPU chips all the time
- Deepseek (a Chinese Startup specializing in AI) showed how it used old Nvidia GPUs to build the best LLM globally to date
- The Nvidia stock price fell 18% in one day – largest Market Cap daily loss ever

Back to the Problem Statement: Some Background

- 95% of ALL health product applications (HPAs) in Africa are linked to Generics
- Generic Application Dossiers are made up of PDFs mainly.
- Some countries have adopted a Risk Classification Tool, but processing is still manual (labor intensive)
- Very Large backlog + Constant new applications
- Total number of outstanding applications is well over 50,000 across Africa



The Challenge – Can we help improve these turnaround times using AI?

Current NRA Workflow: New Health Product Application (Generic)

New Application
PDF (structure + scanned) documents

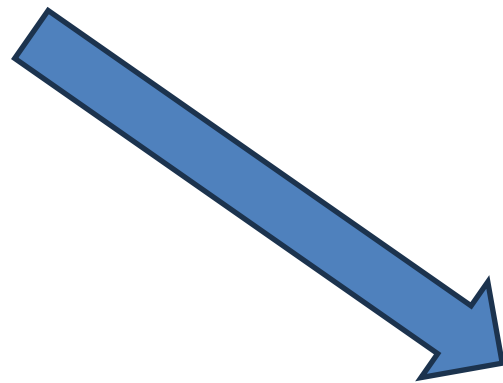


Manual Review Process
Manual Risk Based Analysis Approach
High Risk = Full manual Review
Medium/Low Risk = Smaller review, but still manual
Feedback to Applicant




APPROVED

- 1,000+ Documents per Application
- Some documents have 1,000+ Pages
- Some Dossiers are > than 15Gb



Timeline
between 4 and
30+ months

REJECTED



The limitation of email servers result in applicants having to send multiple emails linked to the same generic drug registration

- Email 1 of x
- Email 2 of x
- Email 3 of x
-



Updated NRA Workflow: New Health Product Application (Generic)

Application #BOA230123/123

Please fill in all details for your application

Application Information

Submission Information
 Procedure Type: Botswana National Procedure
 Evaluation Form: Priority

Product Information
 Botswana Pharmaceutical Classification: Anatomical Therapeutic Chemical (ATC) Classification
 Select Type: [Dropdown]
 Submission Detail: Masters
 Route of Administration: Select Route
 Dosage Form: Select Type

Bio Equivalence Study Information
 CRO Name: [Text]
 Bio Study Number: [Text]

API And Manufacturer Information
 API Manufacturer Number Type: CEP Number: 123445
 Search API: [Text]
 API Manufacturer Number Type: APMF Number: 123445
 Search API: [Text]

Manufacturing Information
 Selected Name: Example Manufacturer
 Manufacturer Role: [Dropdown]
 Primary Packer
 Secondary Packer
 Label

Buttons: Previous, Save

Order #3492
 Date Issued: 25/08/2020
 Date Due: 29/08/2020
 Reference: HJS400029/VitalCare

Applicant details: Jason Edison, VitaCare Clinics, 810 Gaborone, Botswana, +267 373 1720, +267 318 6254

Application details: Application Number: #abcdehgh, Submission Number: 24000001, Sequence Type: Initial

Payment details: Total Due: BWP 9034.87, Bank name: BANK OF BOTSWANA, Country: BOTSWANA, Account: 40-5939-2080, SWIFT code: BBOTBWXG

ITEM	DESCRIPTION	QTY	PRICE
AMRP (NCE) - 1st Strength	Registration for first strength	1	BWP 82809.68
AMRP (NCE) - Add Strength	Additional strength	1	BWP 32825.46

Subtotal: BWP 115635.14
 Discount: BWP 0
 Total: BWP 115635.14

Select Payment Method: Credit Card, EFT
 Download Order
 Upload your proof of payment
 Total Due: BWP 9034.87, Bank name: BANK OF BOTSWANA, Country: BOTSWANA, Account: 40-5939-2080, SWIFT code: BBOTBWXG
 Upload File
 Please accept the payment T&C's before making a payment.
 Submit Proof

DOSSIER RISK MATRIX

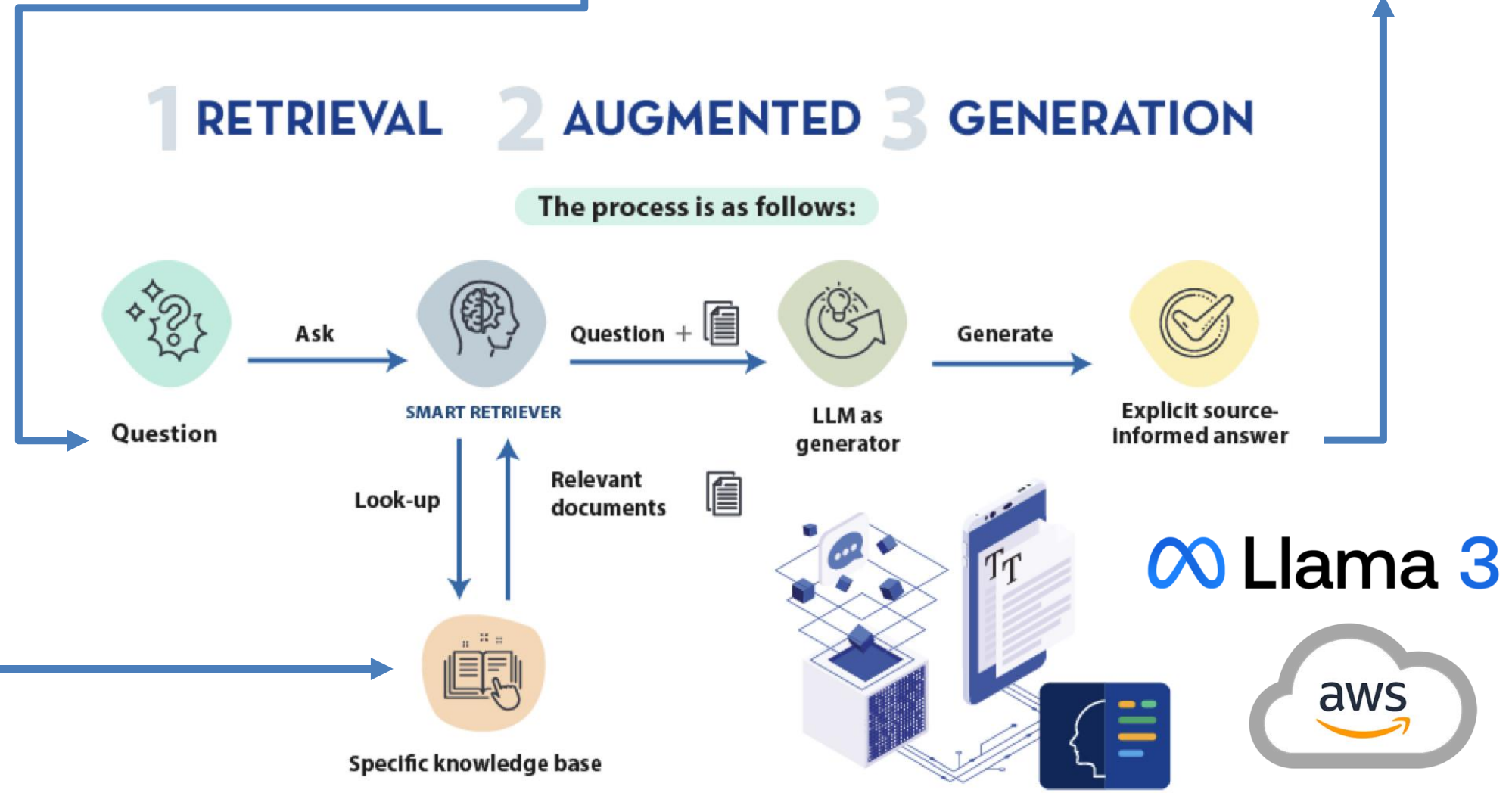
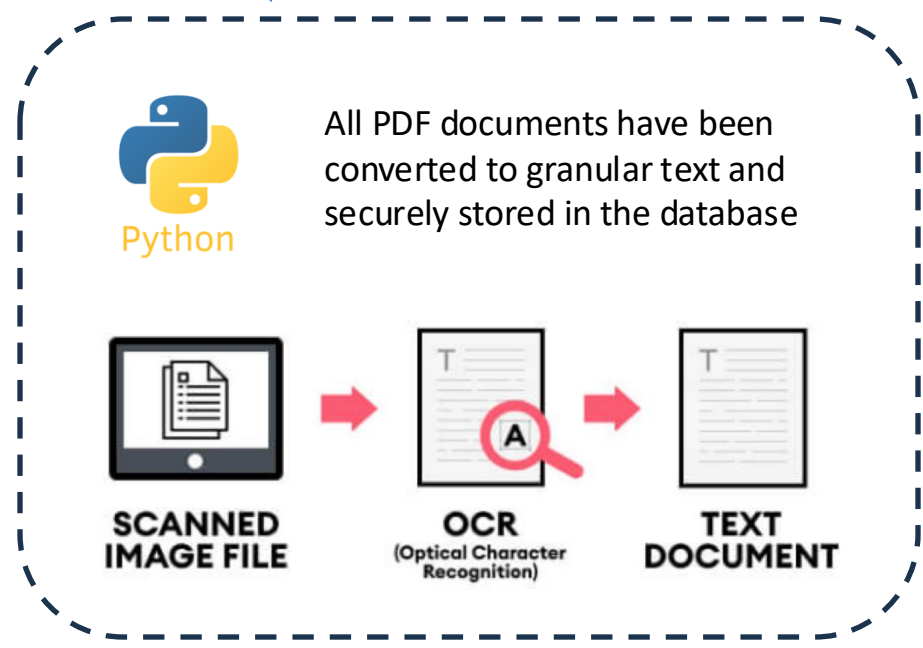
Risk Matrix	Minor	Moderate	Major	Critical
76-100%	0	0	0	2
51-75%	2	0	5	0
26-50%	0	3	0	0
0-25%	1	12	0	0

Likelihood

APPROVED REJECTED

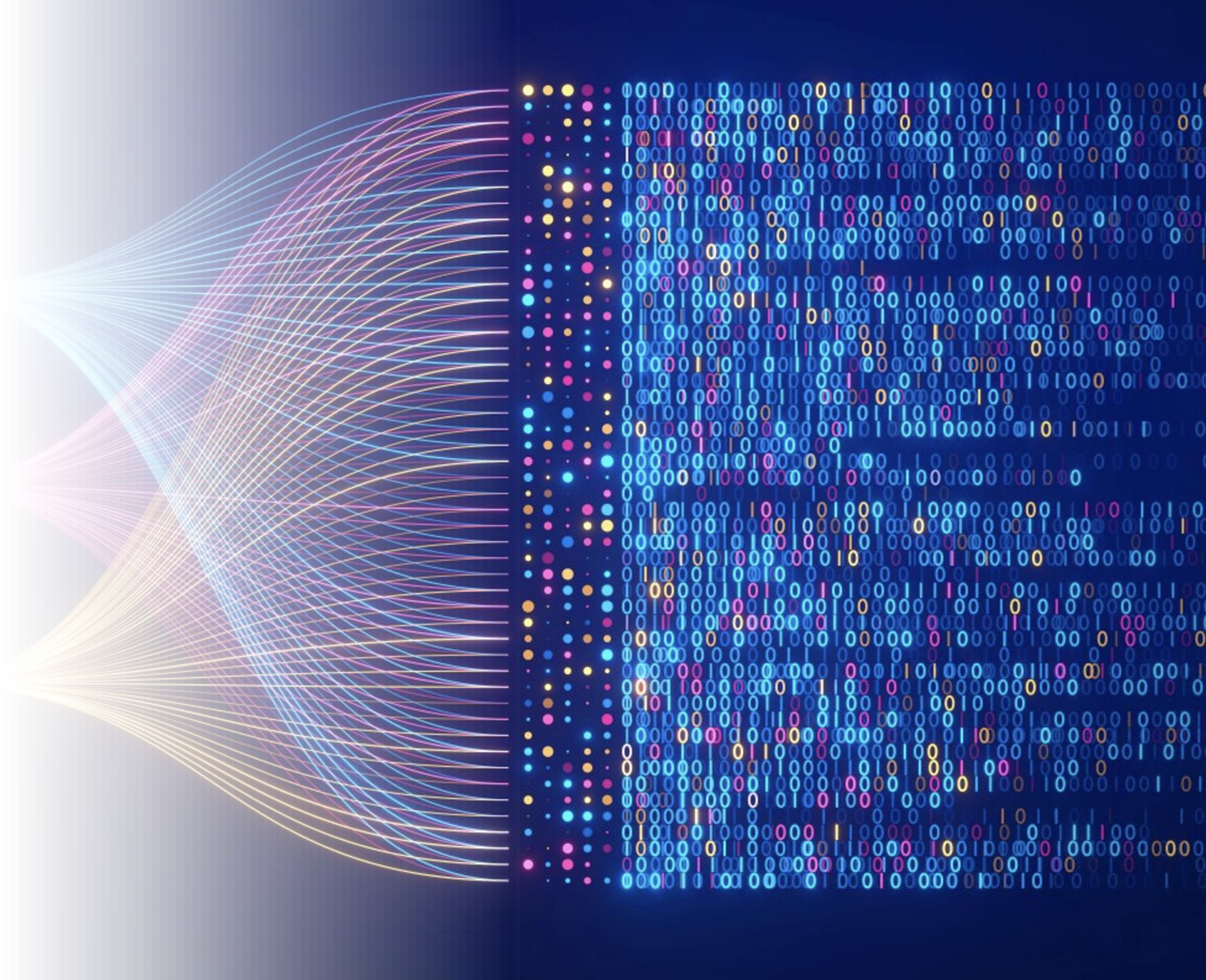


Upload all Dossier related documents to a secure Web-Portal provided by the NRA



WHAT NEXT?

- CRAs + CTAs = AI Assisted Clinical Data Scientists
- DMs = CRF Structure Engineers
- DOMs = Data Review Architects
- PV Officers = AI Safety Bots





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